
Counsel to the Inquiry Paper

Summary of Regulators' Evidence

Introduction

1. In April and August 2026, the Inquiry sent requests for evidence to healthcare regulatory and oversight bodies in England requesting information concerning their respective roles and responsibilities in the regulation of healthcare technologies, including Oxevision.
2. The Inquiry has already heard oral evidence from the Medicines and Healthcare products Regulatory Agency ("**MHRA**") and NHS England. This paper summarises the written evidence provided by other organisations relating to oversight and regulation of healthcare technologies. Those organisations are:
 - a. The British Standards Institution ("**BSI**");
 - b. The Care Quality Commission ("**CQC**");
 - c. The Department of Health and Social Care ("**DHSC**"); and
 - d. The National Institute for Health and Care Excellence ("**NICE**").

DHSC

3. DHSC's evidence is set out in the third and fourth witness statements of William Vineall, dated 20 May 2026 and 14 September 2026 respectively. Mr Vineall is DHSC's Director for NHS Quality, Safety and Investigations, a role he has held since 2020.¹
4. Mr Vineall outlines that DHSC's role in relation to the use of technology and devices in healthcare is "*focused on setting the overarching policy framework and strategic direction*".² This has been reflected in a series

¹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [4]

² *Third Witness Statemen of William Vineall*, 20.05.2026 [DHSC024292], [6]

of policy papers and strategies published in recent years, including the UK's inaugural Medical Technology Strategy ("**the MedTech Strategy**").³ The MedTech Strategy set out the government's priority areas for medical technology and ambition to support the delivery of products that are safe for all, clinically effective, innovative and sustainable.⁴ The MedTech Strategy was followed in July 2025 by '*Fit for the future: 10 Year Health Plan for England*'. This plan set out the government's plan to "reinvent" the NHS through, amongst other things, a shift from "analogue to digital".⁵ The plan emphasised the importance of driving innovation in healthcare, and that regulatory bodies "*must continue to develop agile, risk-proportionate pathways for evaluating and approving products*".⁶

5. In 2021, DHSC established a Medical Technology and Innovation Directorate ("**MTID**"). The MTID focuses on removing structural barriers to the adoption of technology by streamlining adoption pathways and working with the MHRA on medical device regulatory reform.⁷ The MTID does not, however, become directly involved in managing concerns raised about a particular device,⁸ and did not receive any concerns relating to vision-based monitoring systems or Oxevision specifically.⁹
6. DHSC's role does not directly encompass the assessment, management and monitoring of risks and patient safety implications

³ Third Witness Statement of William Vineall, 20.05.2026 [DHSC024292], [8]; WV4-2: Policy Paper, Medical technology strategy, undated [DHSC024327]

⁴ Third Witness Statement of William Vineall, 20.05.2026 [DHSC024292], [9]; WV4-2: Policy Paper, Medical technology strategy, undated [DHSC024327], p. 7

⁵ Third Witness Statement of William Vineall, 20.05.2026 [DHSC024292], [12]; WV4-6: *Fit for the future - 10 Year Health Plan for England*, 22.01.2025 [DHSC024294]

⁶ Third Witness Statement of William Vineall, 20.05.2026 [DHSC024292], [14]

⁷ Third Witness Statement of William Vineall, 20.05.2026 [DHSC024292], [15]-[16]

⁸ Fourth Witness Statement of William Vineall, 14.09.2026 [DHSC028327], [15]

⁹ Fourth Witness Statement of William Vineall, 14.09.2026 [DHSC028327], [16]

of new technologies. Rather, arms-length bodies (“**ALBs**”), such as the MHRA, undertake these functions.¹⁰ They remain accountable to the Secretary of State for Health and Social Care and Parliament in discharging their functions.¹¹ DHSC does not review or approve clinical or operational guidance produced by ALBs, as they operate with statutory independence.¹²

7. Mr Vineall’s statement then summarises the roles of different health and care bodies:

- a. Primary responsibility for overseeing NHS trusts lies with NHS England and the CQC.¹³ NHS England has day-to-day responsibility for the delivery of NHS services and is under a duty to monitor trusts and integrated commissioning boards in their performance.¹⁴ The CQC monitors the quality and safety of NHS care by way of inspections and reports, sharing concerns with other regulators, and taking regulatory action where appropriate.¹⁵
- b. The MHRA is an executive agency of DHSC whose role is to regulate the UK medical devices market.¹⁶ Although it is the responsibility of individual NHS trusts to procure, evaluate and deploy new technologies,¹⁷ the MHRA ensures the safety, quality and effectiveness of medical devices.¹⁸ It relies on approved bodies to assess the regulatory compliance of devices.¹⁹

¹⁰ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [17]

¹¹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [19]-[20]

¹² *Fourth Witness Statement of William Vineall*, 14.09.2026 [DHSC028327], [18]

¹³ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [21]

¹⁴ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [22]

¹⁵ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [27]-[28]

¹⁶ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [30]-[31]

¹⁷ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [29]

¹⁸ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [32]

¹⁹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [35]

- c. Finally, Mr Vineall summarises the respective roles of the Patient Safety Commissioner,²⁰ NICE,²¹ the National Institute for Health and Care Research (“**NIHR**”),²² and the NHS Innovation Service,²³ all of which have supplementary or advisory roles in relation to medical devices and technology.
-
8. In relation to vision-based monitoring systems such as Oxevision, Mr Vineall confirms that DHSC “*is reliant on the work of the ALBs such as the MHRA, CQC and others to provide the regulation, research and guidance for the use of new technologies.*”²⁴ Nonetheless, DHSC has supported the work of ALBs in this respect. For instance:
 - a. In June 2023, DHSC supported work by NHS England and the NIHR to undertake a rapid review of the impacts of surveillance methods on acute wards.²⁵ This was followed by the publication of a further systematic review in November 2024.²⁶
 - b. DHSC policy and research leads engaged with the Health Services Safety Investigations Body (“**HSSIB**”) after HSSIB published its report, ‘Mental health inpatient settings: Creating conditions for the delivery of safe and therapeutic care to adults’, in October 2024. This did not result in further research being commissioned.²⁷
 9. In addition, DHSC recently published guidance for NHS trusts on how to purchase medical technology. This guidance emphasised the

²⁰ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [40]-[41]

²¹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [42]

²² *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [43]-[44]

²³ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [45]

²⁴ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [49]

²⁵ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [50]

²⁶ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [50]; WV4-17: *The use and impact of surveillance-based technology initiatives in inpatient and acute mental health settings: a systematic review*, 09.04.2024 [DHSC024324]

²⁷ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [59]

importance of investing in technology, and urged a “*fundamentally different approach to procurement that is applied consistently across the health service.*”²⁸

10. LIO approached DHSC “*on several occasions to share information and seek discussions regarding its technology.*”²⁹ This included seeking input in NHSE’s rapid review,³⁰ and attending a meeting with a special adviser in DHSC.³¹ It is not known what was discussed at this meeting.³²
11. DHSC has been made aware of concerns relating to the use of vision-based monitoring technology on several occasions. For instance, in January 2025, DHSC responded to written Parliamentary questions which raised concerns relating to the use of vision-based monitoring systems in inpatient settings,³³ and the impact of Oxevision use in particular.³⁴ In responses to both questions, the Parliamentary Under-Secretary of State at DHSC referred to the NHS England rapid review.

CQC

12. CQC’s evidence is set out in the first and second witness statements of Craig Howarth, dated 1 June 2026³⁵ and 7 September 2026³⁶ respectively. Mr Howarth is a Deputy Director for Mental Health in the North region for CQC,³⁷ having previously held the role of Interim Head

²⁸ *Fourth Witness Statement of William Vineall*, 14.09.2026 [DHSC028327], [23]; WV6-02: *Value based procurement national standard guidance for medical technology*, 11.06.2026 [DHSC028330]

²⁹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [65]

³⁰ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [66]

³¹ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [67]

³² *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [68]

³³ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [70]; WV4-44: *PQ - Mental Health Services: Technology (Question for DHSC)*, 05.07.2023 [DHSC024298]

³⁴ *Third Witness Statement of William Vineall*, 20.05.2026 [DHSC024292], [71]; WV4-45: *PQ: Oxevision - Question for DHSC*, 22.01.2025 [DHSC024301]

³⁵ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360]

³⁶ *Second Witness Statement of Craig Howarth*, 07.09.2026 [CQC028145]

³⁷ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [1]

of Inspection in the East of England region for Mental Health. This portfolio included oversight of Essex Partnership University NHS Foundation Trust (“**EPUT**”).³⁸

13. Mr Howarth outlines that, in terms of emerging health technologies, CQC does not generally undertake independent analysis of any potential risks. This is because it is the responsibility of providers to make such decisions, taking into account the evidence base.³⁹ Nor does any assessment of the claims and assurances made by technology manufacturers fall within CQC’s remit.⁴⁰
14. CQC would, however, analyse specific issues arising in relation to the deployment of technology on case-by-case basis through inspections,⁴¹ and through the discharge of its regulatory functions⁴² and by reference to the CQC’s Single Assessment Framework.⁴³ Therefore, should a provider use technology such as Oxevision in a way that contravenes official guidance, this would be commented on by inspectors.⁴⁴
15. Mr Howarth was asked to comment specifically on CQC’s published case study on the ‘Digital Care Assistant’ technology, now known as Oxevision. His first statement outlines the following:
 - a. CQC published a series of case studies on its website in July 2019 relating to the potential of technology to drive improvements in the healthcare system, under the umbrella of ‘Driving

³⁸ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [2]

³⁹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [60]

⁴⁰ Second Witness Statement of Craig Howarth, 07.09.2026 [CQC028145], [25]

⁴¹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [61]

⁴² First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [62]

⁴³ Second Witness Statement of Craig Howarth, 07.09.2026 [CQC028145], [10]

⁴⁴ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [66]

improvement through technology'.⁴⁵ Oxevision was one of the examples provided of *"innovative use[s] of technology"*.⁴⁶

- b. The publication of such case studies was driven by an internal decision on the part of CQC, led by its Independent Voice Panel,⁴⁷ to showcase examples of healthcare providers *"using technology in innovative ways to improve outcomes for people who use services"*.⁴⁸
- c. Its objective in publishing the case studies was *"to demonstrate the potential technology has to play a major part in how health and social care are provided, and in improving health and care, and that CQC welcomes innovation as long as it is not at the expense of quality."*⁴⁹
- d. This reflects CQC's position that it will *"encourage innovation and technology, including AI, where it benefits people and where the innovation supports high-quality, safe and equitable health and social care"*.⁵⁰ However, CQC did not plan to complete any research on those technologies or otherwise publish any commentary or conclusions on their use.⁵¹
- e. In November 2018, the CQC changed its planned approach to the publication of the case studies, deciding not to frame the case studies *"as a cause/effect/a manual of how to improve"*.⁵²
- f. CQC's Independent Voice Panel considered the 'Driving improvement through technology' proposal in December 2018 and approved its progression.⁵³ During discussion of the

⁴⁵ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [11]

⁴⁶ Ibid.

⁴⁷ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [21]

⁴⁸ Independent voice proposal form, 01.06.2018 [CQC024357], p. 1

⁴⁹ Independent voice proposal form, 01.06.2018 [CQC024357], p. 2

⁵⁰ Second Witness Statement of Craig Howarth, 07.09.2026 [CQC028145], [13]

⁵¹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [23]

⁵² E-mail, FOR ACTION: Driving Improvement IV Proposals, 27.11.2018 [CQC024354]

⁵³ Independent Voice Panel meeting notes, 04.12.2018 [CQC024355]

proposal, the Panel asked CQC to consider the types of interventions being used by providers and whether these were having effects on service users and their privacy.⁵⁴ It is not known how this comment was specifically addressed.

16. Mr Howarth emphasises that the CQC “*does not endorse any particular product, supplier or service*”, and that the case studies were provided “*as a basis for discussion*”.⁵⁵ It was not considered that the case studies would be perceived as endorsements or encourage other trusts to deploy the technology.⁵⁶ Trusts were reminded to obtain their own professional or specialist advice.⁵⁷
17. The use of Oxevision by Coventry and Warwickshire NHS Foundation Trust was selected by CQC following an initial intelligence-gathering exercise.⁵⁸ During its inspection report on the Trust in December 2018, CQC had noted the use of Oxevision in Coventry and Warwickshire as “*outstanding practice*”, with staff identifying a reduction in falls since its deployment.⁵⁹ The inspector who carried out the comprehensive inspection preceding that report recalled that they discussed the topic of consent to use Oxevision with the Trust. The Inspector could not recall the details of that conversation, “*but believes that they were sufficiently reassured by CWPT’s response that this did not prompt any additional probing nor any concerns*”.⁶⁰ The report was further subject to the CQC’s usual sign-off process, which includes review by its National Quality Assurance Group, albeit no mental health clinicians

⁵⁴ *Independent Voice Panel meeting notes*, 04.12.2018 [CQC024355], p. 2

⁵⁵ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [52]

⁵⁶ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [53]

⁵⁷ *Ibid.*

⁵⁸ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [35]

⁵⁹ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [45]

⁶⁰ *First Witness Statement of Craig Howarth*, 01.06.2026 [CQC024360], [47]

were involved in the CQC's determination that the use of Oxevision constituted outstanding practice.⁶¹

18. Concerns were raised internally at the time that some of the case studies were presented in highly positive terms "*without there being a proper evaluation (yet) or evidence from [CQC] inspectors to rely on*".⁶² It was further noted that some of the examples included as case studies had "*varying levels of evidence against them, in some cases pretty strong*".⁶³ Mr Howarth states that a number of amendments were made to the draft case studies in response to these concerns.⁶⁴ However, CQC did not undertake any assessments or analysis of its own prior to the publication of the case study.⁶⁵ The wording of the case study was also agreed in advance with Coventry and Warwickshire prior to publication.⁶⁶
19. Mr Howarth reflects on this process in his first witness statement and states that he "*would have expected that CQC request data/information from the Trust to corroborate some of these statements in the report*".⁶⁷ While that information was requested, the Trust stated that research was "*still ongoing*" and that the hypothesis that Oxevision helped to prevent falls "*was being explored*".⁶⁸ Mr Howarth's view is that, without such corroboration being provided, he would not agree with the assessment that the use of Oxevision

⁶¹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [50]

⁶² E-mail, *Driving improvement through technology*, 26.06.2019 [CQC024351]

⁶³ *Ibid.*

⁶⁴ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [39]

⁶⁵ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [57]

⁶⁶ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [36]

⁶⁷ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [58]

⁶⁸ *Ibid.*

represented “*outstanding practice*.”⁶⁹ The case study is not currently on the CQC’s website.⁷⁰

20. Beyond the consideration of Oxevision in the context of preparing the case study, Mr Howarth also outlines that CQC became aware of concerns relating to Oxevision in August 2023, when it was contacted by Stop Oxevision.⁷¹ Stop Oxevision raised concerns about what it described as “CQC’s *apparent endorsement of Oxevision*”.⁷² Following this contact, a series of meetings took place between Stop Oxevision and senior CQC figures, including then-CEO Ian Trenholm. At a meeting in November 2023, Stop Oxevision raised concerns relating to consent, data protection, psychological impact on patients and CQC’s position.⁷³ In parallel, CQC engaged with NHS England, which asked CQC to develop a policy position on the use of vision-based monitoring systems.⁷⁴ This led to CQC developing its ‘Brief guide: Digital contactless patient monitoring technologies in mental health inpatient services,’ and an accompanying webpage.⁷⁵ CQC also commissioned an independent evidence review into vision-based monitoring systems, completed in July 2025.⁷⁶
21. Separately to the above, Mr Howarth outlines several other relevant regulatory actions taken by CQC. These have been set out in previous evidence disclosed by CQC to the Inquiry. In sum, the action taken includes:

⁶⁹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [59]

⁷⁰ <https://www.cqc.org.uk/publications/themes-care/digital-care-assistant> (Accessed 13 September 2026)

⁷¹ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [75]

⁷² Email, Concerns in relation to Oxevision/Oxehealth, 24.08.2023 [CQC024339]

⁷³ Notes of meetings with Oxevision, Undated [CQC024343]

⁷⁴ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [80]

⁷⁵ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [80]-[82]

⁷⁶ Exploring evidence regarding vision-based monitoring in inpatient mental health units, 01.07.2025 [CQC024335]

- a. In October 2022, several management review meetings (“**MRMs**”) were held to consider the findings of CQC’s 2022 inspection of EPU. This identified, amongst other issues, concerns with EPUT’s processes for obtaining staff consent to the use of Oxevision. CQC noted during that inspection that several patients were not aware that cameras were installed in their bedrooms.⁷⁷ There followed a process of engagement between CQC and EPUT, eventually resulting in CQC issuing a warning notice to ensure action was taken.⁷⁸ These steps are set out in further detail in the First Witness Statement of Stuart Dunn, dated 13 April 2026.⁷⁹
- b. CQC inspected EPUT’s acute wards for working-age adults and psychiatric intensive care units again in November and December 2024. The inspection report, dated 11 July 2025, considered that action had been taken to respond to its previous concerns. The report concluded that EPUT “*ensured patients understood the use of the contact-free patient monitoring system and sought consent*”.⁸⁰

NICE

22. NICE’s evidence is set out in the witness statement of Jonathan Benger CBE, Chief Executive of NICE, dated 13 May 2026. His statement is 15 pages long and accompanied by 9 exhibits.⁸¹
23. NICE was established in 1999 as a Special Health Authority, subsequently re-established as an arms-length body of DHSC.⁸² Mr

⁷⁷ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [87]

⁷⁸ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [90]

⁷⁹ First Witness Statement of Stuart Dunn, 13.04.2026 [CQC021212]

⁸⁰ First Witness Statement of Craig Howarth, 01.06.2026 [CQC024360], [95]

⁸¹ Witness Statement of Jonathan Benger in response to Rule 9(2), 13.05.2026 [NICE023320]

⁸² Witness Statement of Jonathan Benger in response to Rule 9(2), 13.05.2026 [NICE023320], [8]-[9]

Benger's statement outlines that the role of NICE is to help ensure that people have equal access to clinically and cost-effective treatments by, amongst other things, producing guidance and recommendations for health and care practitioners and providing independent assessment of the evidence base for new health technologies.⁸³

24. NICE produces several different kinds of guidance, including:

- a. Guidelines: these are evidence-based recommendations for health and care in England which assist professionals to improve health and care services, with topics commissioned by NHS England.⁸⁴ Topics for guidelines are commissioned by NHS England.
- b. Quality standards: these documents set out priority areas for quality improvement in health, public health and social care for the benefit of commissioners, service providers and practitioners.⁸⁵
- c. Health technology evaluations: these are evaluations designed to provide recommendations on the clinical and cost effectiveness of new and existing medicines, health technologies and treatments in the NHS,⁸⁶ in accordance with NICE's technology appraisal and highly specialised technologies guidance manual.⁸⁷ Commissioners and NHS England are required to fund technologies recommended

⁸³ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [9]

⁸⁴ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [22]

⁸⁵ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [24]

⁸⁶ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [25]

⁸⁷ *NICE technology appraisal and highly specialised technologies guidance: the manual*, 31.03.2026 [NICE022537]

through health technology evaluations.⁸⁸ The processes that NICE follows when evaluating health technology products are set out in the HealthTech Programme Manual.⁸⁹

25. While NICE produces guidance on the effectiveness of health technologies, it is not responsible for assessing the patient care and safety implications of new technologies that are deployed, or proposed to be deployed, in the NHS.⁹⁰ Its view is that primary responsibility for such matters rests with the MHRA and the manufacturer of the technology.⁹¹ Nonetheless, Mr Benger acknowledges the importance of patient safety, and states that NICE works closely with the MHRA to ensure that NICE guidance remains aligned to the regulatory status of individual healthcare products.⁹²
26. NICE has been made aware of concerns relating to the use of Oxevision on two occasions:
 - a. In June 2024, NICE was contacted by a member of the public raising concerns relating to the care of their late partner at a mental health inpatient unit not in Essex. Those concerns included that Oxevision, which was in use on the ward, had not alerted staff to the deceased's physical deterioration.⁹³ NICE's

⁸⁸ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [27]

⁸⁹ *NICE HealthTech programme manual*, 17.12.2025 [NICE022540]

⁹⁰ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [31]-[32]

⁹¹ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [31]

⁹² *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [37]-[38]

⁹³ *Correspondence between NICE and a complainant relating to Oxevision*, 01.06.2024 [NICE022538]

view was that it was not responsible for assessing the safety of Oxevision, and no further action was taken.⁹⁴

- b. In May 2025, NHS England shared with NICE a confidential market intelligence report on vital signs monitoring technologies, which made reference to concerns relating to Oxevision. This was not a formal request for NICE to assess Oxevision's effectiveness.⁹⁵

- 27. NICE has not undertaken any assessments of Oxevision, and currently has no plans to evaluate it or similar vision-based patient monitoring systems for the purposes of producing NICE guidance.⁹⁶

BSI

- 28. BSI's evidence is set out in the witness statement of Graeme Tunbridge dated 24 September 2026.⁹⁷ Mr Tunbridge is the Senior Vice President, Global Regulatory and Quality at BSI. Prior to joining BSI in January 2022, he was the Director of Devices at the MHRA.⁹⁸
- 29. BSI is organised as a global group of companies that operates in several jurisdictions ("**BSI Group**"). In the UK, BSI is a company incorporated by Royal Charter which acts as the UK's National Standards Body.⁹⁹ The activities of the BSI Group include standards development, testing, inspection, certification and regulatory compliance services.

⁹⁴ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [51]

⁹⁵ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [48]

⁹⁶ *Witness Statement of Jonathan Benger in response to Rule 9(2)*, 13.05.2026 [NICE023320], [47]-[48]

⁹⁷ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561]

⁹⁸ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [1]-[2].

⁹⁹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [6] – [7].

30. In the medical devices sector, BSI's activities include operating as a conformity assessment body within the European Union ("**EU**") and the UK under the applicable legislative framework.¹⁰⁰ Specifically:
- a. Prior to the UK's withdrawal from the EU, BSI operated its medical device assessment and certification business as a "Notified Body" under EU legislation, which empowered BSI to assess and certify compliance with EU medical devices regulations. These functions were discharged through its separate legal group entity, BSI Assurance UK Limited. The MHRA provided oversight of these functions.¹⁰¹
 - b. Following the UK's exit from the EU, BSI Assurance UK Limited became a UK "Approved Body", designated and supervised by the MHRA.¹⁰²
31. BSI's conformity assessment activities include assessment of a manufacturer's quality management system ("**QMS**"),¹⁰³ review of technical documentation, review of clinical evaluation reports, and assessment of post-market surveillance and vigilance systems.¹⁰⁴ Mr Tunbridge notes that BSI "*does not undertake independent product testing as part of the conformity assessment process.*"¹⁰⁵ Instead, it "*independently evaluates the adequacy, relevance and sufficiency of*

¹⁰⁰ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [6] – [7].

¹⁰¹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [7] – [8].

¹⁰² *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [9].

¹⁰³ Manufacturers are required to establish and maintain processes and procedures that ensure devices are consistently designed, manufactured and controlled in accordance with applicable regulatory requirements (*Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [15]).

¹⁰⁴ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [11].

¹⁰⁵ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [12].

the evidence presented by the manufacturer against the applicable regulatory requirements.”¹⁰⁶ Certification may be issued if BSI is satisfied that the manufacturer has demonstrated conformity.¹⁰⁷

32. The manufacturer is responsible for generating, maintaining and presenting information to demonstrate compliance. 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 (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.¹⁰⁸
33. Mr Tunbridge explains that 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. Therefore, conformity assessment does not necessarily involve a product-by-product assessment of every device covered by a certificate.¹⁰⁹
34. As to BSI's role in relation to wider patient safety and regulatory oversight, Mr Tunbridge states that the regulatory framework assigns primary responsibility for patient safety and emerging risks associated with medical technologies to the manufacturer and the competent

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

¹⁰⁸ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [13]-[14].

¹⁰⁹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [23].

authority.¹¹⁰ Whilst BSI assesses whether a device meets the applicable regulatory requirements, decisions regarding procurement, deployment, and the broader clinical impact of a technology are generally matters for healthcare providers and professionals.¹¹¹ BSI does not hold primary responsibility for assessing the wider patient care implications of new technologies deployed within healthcare systems, nor for determining how they should be deployed.¹¹²

35. 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.¹¹³
36. 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.¹¹⁴
37. BSI's responsibilities are the post-certification surveillance activities it undertakes, which are intended to verify continued compliance with the applicable regulatory requirements. These activities may include QMS audits, technical documentation reviews, review of post market

¹¹⁰ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [28].

¹¹¹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [29].

¹¹² *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [29].

¹¹³ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [30].

¹¹⁴ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [30].

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.¹¹⁵

38. While BSI undertakes conformity assessment and certificate activities as an Approved Body, the MHRA acts as the Competent Authority and regulator responsible for market surveillance, enforcement and oversight of Approved Bodies. BSI and MHRA therefore fulfil complementary but distinct functions within the overall regulatory framework.¹¹⁶

39. As to the certification of LIO devices:

- a. The “Oxecam” device was certified on 10 September 2018. 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, BSI was notified of a name change of the device to Vital Signs.¹¹⁷
- b. Following the UK’s exit from the EU, on 5 September 2023, Vital Signs was certified as a Class IIa device. On 13 May 2025, the scope of the certification was amended to include the Oxevision Sleep System.¹¹⁸

¹¹⁵ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [33].

¹¹⁶ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [36].

¹¹⁷ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [41].

¹¹⁸ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [42].

- c. On 25 September 2024, Vital Signs and Oxevision Sleep System devices were certified as Class IIa devices.¹¹⁹

40. As Oxevision Sleep System is a software-only medical device, the only component of the overall product that requires conformity assessment is the software element of the product.¹²⁰ BSI does not access the software or test it as part of the conformity assessment. Instead, “*BSI maintains specific processes and procedures for the assessment of a software-only device based on the current state of the art.*”¹²¹
41. In relation to safety concerns over Oxevision devices, Mr Tunbridge explains that the manufacturer is responsible for monitoring its devices after they are placed on the market and ensuring continued compliance with regulatory requirements. Notified and Approved Bodies support vigilance by reviewing manufacturers’ vigilance procedures, auditing their implementation, and liaising with Competent Authorities where appropriate. Notified Bodies and Approved Bodies are generally required to review the manufacturer’s vigilance data during periodic surveillance audits.¹²² Manufacturers must also submit vigilance data directly to BSI.¹²³
42. There were four incident reports for the Vital Signs device during the Inquiry’s Relevant Period.¹²⁴

¹¹⁹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [41], [43].

¹²⁰ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [46].

¹²¹ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [47] – [48].

¹²² *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [52] – [53].

¹²³ *Witness Statement of Graeme Tunbridge in response to Rule 9(1)*, 24.09.2026, [BSI028561], [54].

¹²⁴ 1 January 2000 to 31 December 2023.

- a. On 15 February 2023, Oxehealth Limited ("**Oxehealth**") reported to BSI that the Vital Signs software at one customer site produced erroneous constant pulse rate readings due to environmental power issues. Oxehealth 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.¹²⁵
- b. On 19 December 2022, Oxehealth reported to BSI that its Vital Signs software produced incorrect pulse rate readings due to *"intermittent instability in the output of the infrared illuminators"* caused by failing power supplies. The issue was *"proactively detected"* with *"no reported customer complaints or health impacts on patients"*. Oxehealth replaced defective updates. BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.¹²⁶
- c. On 3 November 2022, Oxehealth Limited reported to BSI that its Vital Signs software occasionally produced incorrect pulse rate readings for one specific patient. 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. BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.¹²⁷
- d. On 22 March 2022, Oxehealth Limited reported to BSI that its Vital Signs software erroneously reported a pulse rate of "50

¹²⁵ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSIO28561], [55(i)].

¹²⁶ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSIO28561], [55(ii)].

¹²⁷ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSIO28561], [55(iii)].

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.”* Corrective actions were taken. BSI reviewed and closed the incident, with the actions taken by the manufacturer considered appropriate and no wider adverse trends noted.¹²⁸

- e. In relation to the incidents reported in the 22 March 2022 and 19 December 2022 reports, Oxehealth initiated a Field Safety Corrective Action, following which the MHRA issued Field Safety Notices.¹²⁹

¹²⁸ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [55(iv)].

¹²⁹ Witness Statement of Graeme Tunbridge in response to Rule 9(1), 24.09.2026, [BSI028561], [55(ii)] and [(iv)].