FIRST WITNESS STATEMENT

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Response to request for information concerning the deployment of new technologies in healthcare settings and the Oxevision system dated 16 April 2026

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1. The MHRA is an executive agency of the Department of Health and Social Care (DHSC). This means that it is legally indistinguishable from the Secretary of State. However, it is operationally independent. Under the Carlton principle, the MHRA acts and takes decisions on behalf of the Secretary of State. The MHRA was formed in 2003 following the merger of the Medicines Control Agency and the Medical Devices Agency. In 2013 the MHRA merged with the National Institute for Biological Standards and Control (NIBSC). The mission of the MHRA is to protect and promote public health by ensuring that healthcare products work and are acceptably safe.

2. The MHRA is the United Kingdom's regulator of medicines, medical devices, and blood components for transfusion, responsible for ensuring their safety, quality, and effectiveness. Specifically, the MHRA's primary responsibilities are:
    a. Ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and effectiveness;
    b. Ensuring that the supply chain for medicines, medical devices and blood components is safe and secure;
    c. Promoting international standardisation and harmonisation to assure the safety, quality and effectiveness of all medicines;
    d. Helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
    e. Supporting innovation and research and development that are beneficial to public health;
    f. Influencing UK and international regulatory frameworks so that they are risk-proportionate and effective at protecting public health; and
    g. Designating Approved Bodies (ABs) for third party conformity assessments of medical devices in the UK (as of 1 January 2021).

3. It is not the role of the MHRA to approve medical devices for the UK market. The MHRA is responsible for regulating medical devices on the UK market, discharging the functions of the Secretary of State under the Medical Devices Regulations 2002. The Medical Devices Regulations 2002 are “safety regulations” within the meaning of section 11 of the Consumer Protection Act 1987. Key regulatory responsibilities undertaken by the MHRA in relation to medical devices include pre-market assessments of clinical investigations, setting the regulatory framework for the conditions that devices have to meet before being placed on to the market, assessing all allegations of non-compliance brought to us, using a risk-based system, monitoring the activity of UK Approved Bodies designated by MHRA to assess the compliance of manufacturers.

4. The MHRA also has a role in identifying and monitoring emerging and innovative technologies, and reforming the regulatory framework to address these, for example new digital health technologies and artificial intelligence-enabled products used in healthcare settings. This includes collaboration with NHS bodies, clinicians, manufacturers, academic experts and other regulators in relation to safety reporting, regulatory science and evolving standards frameworks.

5. As a result of the UK’s exit from the EU, different provisions apply to the regulation of medical devices in Great Britain from their regulation in Northern Ireland. In Great Britain, devices are regulated under the Medical Devices Regulations 2002. In Northern Ireland (under the terms of the Windsor Framework), devices continue to be regulated by the EU Medical Devices and the In Vitro Diagnostic Medical Devices legislation.

6. It is important to note that the MHRA only regulates products which fall under the definition outlined in Regulation 2 of the Medical Devices Regulations 2002. A medical device under this definition is: any instrument, apparatus, appliance, software, material, or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which:

    a. is intended by the manufacturer to be used for human beings for the purpose of:
        i. diagnosis, prevention, monitoring, treatment or alleviation of disease,
        ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

iii. investigation, replacement or modification of the anatomy or of a physiological process, or
iv. control of conception; and

b. does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means.

7. By Regulation 2 of the Medical Devices Regulations 2002, an ‘in vitro diagnostic medical device’ means a medical device which:
    a. is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and
    b. is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information;
        i. concerning a physiological or pathological state,
        ii. concerning a congenital abnormality,
        iii. to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
        iv. to monitor therapeutic measures and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination.

8. The following are examples of ‘medical devices’ under the definition of the Medical Devices Regulations 2002:
    a. Medical masks and surgical gloves and gowns for healthcare professionals intended to protect the patient;
    b. Ventilators;
    c. Continuous Positive Airway Pressure (“CPAP”) machines;
    d. Lateral flow sample collection kits; and
    e. Polymerase chain reaction (“PCR”) sample collection kits.

9. With respect to the definitions provided by the Medical Devices Regulations 2002, the intended purpose of a product plays a crucial role in determining whether it qualifies as a 'medical device’. If a product is not classified as a medical device, it is not within the scope of the Medical Devices Regulations 2002.

10. Under Regulation 7 of the Medical Devices Regulations 2002 (SI 2002 No 618, as amended), general medical devices are classified into four classes of increasing levels of risk: Class I, IIa, IIb or III in accordance with criteria in the Medical Devices Regulations 2002, Annex IX (as modified by Schedule 2A). These criteria are often called “classification rules”. Examples of classification are given below:

    I. Class I – lowest risk e.g. syringes without needles, medicine spoons, spectacle frames, standard adhesive bandages, examination lights.
    II. Class IIa – e.g. short-term corrective contact lenses, suture needles, standard hearing aids, transcutaneous electrical nerve stimulation (TENS) devices.
    III. Class IIb – e.g. apnoea monitors, ventilators, surgical lasers, diagnostic X-ray sources.
    IV. Class III – highest risk e.g. pacemakers, total hip joint replacements, breast implants, contraceptive IUDs, devices containing medicinal substances.

11. Class I medical devices without a sterile or measuring function are self-certified by the manufacturer of the device. All other device classifications require assessment and assurance markings by a Notified or Approved Body.

Enforcement powers

12. The Medicines and Medical Devices Act 2021 (“MMD Act”) granted the MHRA enhanced enforcement powers, including issuing compliance, suspension, safety notices for non-compliance with the Medical Devices Regulations 2002. Prior to this Act, the MHRA's authority came from the Medical Devices Regulations 2002 and the General Product Safety Regulations 2005. The MMD Act expanded the MHRA's powers, allowing it to issue enforcement notices requiring a ‘person’ to take certain action. We can issue such notices not just to manufacturers, but also to others in the marketing and supply chain. Examples of the notices we can issue under the MMD Act include:
    I. compliance notices, requiring the person to comply with a specified medical devices provision;
    II. suspension notices, restricting the availability of a device in order to protect health and safety;

III. safety notices, imposing prohibitions or requirements on the availability of a device in order to protect health and safety; and

IV. information notices, requiring a person to provide information to MHRA to assist in determining whether to issue a compliance, suspension or safety notice.

13. If we consider it is necessary take action to protect health or safety in relation to a medical device which has already been made available to the public, we can recall that device by taking steps to organise its return. A device may only be recalled if no alternative steps would sufficiently protect health or safety.

Notified Bodies

14. An EU Notified Body is a third-party body which undertakes assessments of medical devices (outside of Class I) to assess whether manufacturers and their medical devices conform with the regulatory requirements set out in EU legislation. These conformity assessment bodies are responsible for providing assurance markings known as ‘CE marks’ described further at paragraph 41. An EU Notified Body is designated and monitored by an EU member state. Before the UK’s exit from the EU on 1 January 2021, all medical devices intended for market in the EU (outside of Class I) were assessed by Notified Bodies for compliance and assurance markings.

Approved Bodies

15. Prior to the UK’s exit from the EU, the MHRA had designated three Notified Bodies: the British Standards Institution (BSI), Underwriter Laboratories (UL) and the General Society of Surveillance (SGS). As of 1 January 2021, with the UK’s exit from the EU, the UK introduced Approved Bodies, the UK equivalent of an EU Notified Body. The MHRA is responsible for the designation and monitoring of Approved Bodies. Approved Bodies for medical devices and IVDs are designated in accordance with the provisions of the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) and Regulation 920/2013. Organisations applying to be a UK Approved Body for medical devices need to obtain UKAS accreditation under ISO 17021.1:2015 for ISO 13485 before the MHRA can designate them as an Approved Body. Applications to both UKAS and MHRA can be made in parallel.

16. Once an organisation has submitted its application to the MHRA for Approved Body status, this is reviewed by the MHRA to assess four key areas in relation to the organisation:
    I. Legal and organisational requirements, including issues relating to independence and impartiality, liability and financial viability.
    II. Ensuring that the organisation has an effective and controlled Quality Management System.
    III. Resource requirements to ensure that the organisation has sufficient numbers of appropriately qualified staff to undertake conformity assessment of the devices seeking designation.
    IV. Process requirements to understand whether the processes and procedures that the Approved Body will implement for conformity assessment are effective and are in accordance with the requirements set out in the regulations and associated guidance.

17. After successful designation, the MHRA monitors UK Approved Bodies including by regular surveillance audits and by witnessing their compliance assessment of manufacturers. Both designation and monitoring are subject to fees.

18. Like Notified Bodies, Approved Bodies assess medical devices intended for market in GB (other than Class I) for conformity with the Medical Devices Regulations 2002. Approved Bodies provide compliant devices with a UKCA mark which allows for medical devices to be placed on the GB market but not the EU. Under the terms of the Windsor Framework, medical devices on the market in NI must comply with EU regulations. Assurance markings are described at paragraph 24.

19. After 1 January 2021, the MHRA automatically rolled over the previous designation of the three Notified Bodies and designated them to act as Approved Bodies. To ensure a smooth transition, CE marked devices were recognised in the GB, initially to 30 June 2023. In 2023 the government introduced measures to extend acceptance of CE marked devices in Great Britain to between 2028 to 2030 depending on which EU legislation the product was certified under. An infographic illustrating these dates can be found here. The first new organisation to be designated by the MHRA as an Approved Body was the Deutscher Kraftfahrzeug-Überwachungs-Verein (DEKRA), appointed on 2 October 2022. At the time of writing there are nine designated approved bodies.

20. Currently, all but one designated UK ABs also have a ‘sister’ EU Notified Body which can issue UKCA and CE marks respectively.

Assurance Marking

21. As described above, it is the role of the Notified and Approved bodies to assess a medical device for assurance marking against regulatory requirements set by the EU or MHRA respectively. Assurance markings signify that a medical device meets specific safety and quality standards, providing assurance to consumers and facilitating market access. Different assurance marks are required according to where the medical device is intended for use, and the timeframe under which it was approved to be placed on the market. The UK Medical Devices Regulations 2002 (as amended) require, since January 2021, that all medical devices whatever their assurance marking, must be registered with the MHRA before being placed on the GB market. Registration on the MHRA’s list of medical devices placed on the GB market is not conditional on an assessment.

22. There are four assurance marks:

i. **CE Mark**: The CE mark signifies that the medical device complies with EU legislation and can therefore circulate freely within the European market, as well as the GB market within the transitional agreements discussed in paragraph 38. Any mandatory third-party conformity assessment for CE marks must be carried out by an EU Notified Body.

ii. **UKCA Mark**: The UK Conformity Assessed (UKCA) mark was introduced on 1 January 2021 and is the UK’s medical device assurance marking. It covers medical devices that previously required the CE mark and indicates that the medical device meets UK requirements. Any mandatory third-party conformity assessment for the UKCA mark must be carried out by a UK Approved Body. The first medical device UKCA certificate was issued by the Approved Body BSI on 29 January 2021.

iii. **CE UKNI / UKNI Mark**: A UKNI mark approved by a UK Notified Body can be used to place a device in circulation in Northern Ireland. This

will not allow circulation in Great Britain or the EU. A CE mark approved by an EU Notified Body can be used to place a device in circulation in both Northern Ireland and the EU. A UKNI mark is required if a medical device is to be placed on the Northern Ireland market only, the medical device requires mandatory third-party conformity assessment, and a UK Notified Body is used to carry out those conformity assessments. To issue a UKNI mark, a conformity assessment body must be designated as a UK Notified Body. To date, no organisations have applied for designation as a UK Notified Body. Medical devices circulating in Northern Ireland are therefore marked with a CE mark approved by an EU Notified Body.

Registration of medical devices

23. Prior to the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) that came into force from 1 January 2021 with the UK's exit from the EU, only Class I medical devices, IVDs, custom-made devices and system or procedure packs needed to be registered. Registration of a device does not represent any form of accreditation, certification, approval or endorsement, but is a requirement for placing a device on the market. A 'system' is a combination of products, either packaged together or not, which are intended to be interconnected or combined to achieve a specific medical purpose. On the other hand, a procedure pack is a combination of devices packaged and marketed together for a specific medical purpose. Manufacturers whose products were being produced overseas who wished to market them in the UK would be required to appoint either a UK or an EU authorised representative to bring their product to market. However, since 1 January 2021, the MHRA only accepts registration of devices, i, from manufacturers where the manufacturer is based in the UK. If the manufacturer is based outside the UK, they must appoint a UK Responsible Person. This UK Responsible Person will then assume certain responsibilities on behalf of the manufacturer as described in the guidance for UK Responsible Persons**,** including registering the device with the MHRA. The UK Responsible Person must provide written evidence that they have the manufacturer's authority to act as their UK Responsible Person.

24. In cases where the Great Britain importer is not the UK Responsible Person, the importer is required to inform the relevant manufacturer or UK Responsible Person of their intention to import a medical device. In such cases, the manufacturer or the

manufacturer's UK Responsible Person is required to provide the MHRA with details of device importers.

25. Obligations also apply in relation to storage, transportation and checking device labels for the CE marking or UKCA marking.

Responsibility of the manufacturer in medical device certification

26. Manufacturers must consider if their product is a medical device before placing it on the market. If their product claims meet the definition of a medical device as outlined at paragraph 19, they must seek appropriate assurance marking. The MHRA has produced extensive guidance on this and readily provides advice to manufacturers about whether their product is a medical device and if so, which class it may fall into.

27. Under the EU Medical Devices Regulation (2017/745) low risk devices such as Class I medical devices (defined at paragraphs 27 to 29), are self-certified by the manufacturers of the device. To self-certify their device, manufacturers are required to check products meet relevant essential requirements, carry out clinical evaluations and notify the MHRA of any proposals to carry out a clinical investigation to demonstrate safety and performance, register with the MHRA and implement and maintain corrective action and vigilance procedures including a systematic procedure to review experience gained in the post-production phase.

28. If a Class I medical device has a measuring function or is sterile, then it cannot be self-certified and requires a third-party conformity assessment by a Notified or Approved Body. Medium and high-risk devices, classified as Class IIa, IIb and III medical devices, such as hip joint implants or cardiac pacemakers, always need to be certified by a Notified or Approved Body.

29. Finally, manufacturers need to demonstrate that their medical device meets the relevant requirements in the UK Medical Devices Regulations 2002 by carrying out an assessment, known as a conformity assessment. The key requirements of a conformity assessment for medical devices include: essential requirements, ensuring devices are designed and manufactured to be safe; clinical evaluation, where manufacturers must evaluate relevant data, often from clinical studies; a quality management system (QMS), which ensures controlled and documented processes for design, manufacturing, and distribution; comprehensive technical documentation providing evidence of the device's

compliance; and a post-market surveillance (PMS) system to monitor device performance and safety after-market release, addressing any adverse events. Depending on the device's classification, the assessment can be done by the manufacturer to self-certify a device or must be done by an Approved, or by a Notified Body.

30. Once a medical device has been placed on the UK market, the manufacturer is required to submit vigilance reports to the MHRA when serious incidents occur in the UK that involve their device and take the appropriate safety action. Since new regulations came into effect in June 2025, manufacturers must comply with updated post market surveillance which incurs more strict reporting requirements. The criteria for incident reporting are provided on the MHRA website. The manufacturer must ensure that their device meets appropriate standards of safety and performance for as long as it is in use.

31. I have been asked whether the roles or functions of the MHRA differ in respect of NHS bodies and private providers delivering NHS-funded care, and if so, how. The MHRA's regulatory role does not differ according to whether a regulated medicine or medical device is intended for use within the NHS or by an independent provider delivering NHS-funded care.

32. The MHRA is responsible for assessing and regulating the safety, quality and efficacy (or, in the case of medical devices, safety and performance) of medicines and medical devices within its statutory remit. However, an MHRA authorisation or approval does not, of itself, determine whether a product will be adopted, commissioned, purchased or used within the NHS or by a particular healthcare provider.

33. Decisions as to whether authorised products are funded, commissioned or used in clinical practice are generally made separately by bodies such as National Institute for Health and Care Excellence ("NICE"), NHS commissioners and individual healthcare providers, including independent sector providers. Those decisions may take into account matters such as clinical effectiveness, cost-effectiveness, operational considerations and local commissioning arrangements, in addition to regulatory approval.

34. The MHRA regulations and conformity assessment play an important role in providing assurance that a medical device placed on the market satisfies the applicable regulatory requirements relating to safety, quality and performance. In that sense, healthcare

providers are entitled to take account of the fact that a device has obtained the relevant regulatory approval or certification when considering whether it may appropriately be procured or used in clinical settings.

35. However, MHRA approval, registration or conformity marking does not of itself constitute a recommendation that a particular device should be procured, adopted or deployed in any specific clinical environment or patient population. Nor does it remove the responsibility of healthcare providers to undertake their own procurement, governance, clinical safety and risk assessment processes.

36. In practice, decisions by NHS Trusts and other providers concerning procurement or deployment of medical devices may also take into account a range of additional considerations, including clinical effectiveness, suitability for the intended clinical context, interoperability with existing systems, staff training requirements, information governance considerations, operational risks, cost-effectiveness, guidance issued by NICE, and local clinical governance arrangements.

37. Accordingly, whilst it may be appropriate for providers to place significant weight upon the fact that a device has satisfied applicable MHRA regulatory requirements, such reliance would ordinarily form only one part of a broader decision-making and risk management process undertaken at local level.

38. The extent of any further assessment required by a provider is likely to depend upon the nature of the device, the degree of clinical risk associated with its use, the setting in which it is to be deployed, and whether the technology is novel, complex or integrated into wider clinical systems or decision-making processes.

39. The MHRA's regulatory role is therefore complementary to, rather than a substitute for, the separate responsibilities of healthcare providers in relation to procurement, implementation, clinical governance and patient safety oversight.

Post market-surveillance and regulatory action

40. The MHRA also exercises a range of post-market regulatory and safety functions in relation to medical devices once they have been placed on the market and are in clinical use. Those functions are intended to support the ongoing identification, assessment, monitoring and mitigation of risks to patient safety associated with medical devices and related technologies.

41. Where safety concerns arise in relation to a medical device, the MHRA may take a variety of regulatory actions depending upon the nature and seriousness of the issue identified. Such actions may follow reports received through the MHRA's vigilance systems, information provided by manufacturers or healthcare providers, international regulatory alerts, published scientific evidence, inspections, or other safety investigations.

42. One form of regulatory action is the issuance or oversight of Field Safety Corrective Actions ("FSCAs") undertaken by manufacturers. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in health associated with the use of a medical device. FSCAs may include software updates, changes to instructions for use, modifications to devices already in circulation, additional warnings, withdrawal of devices from use, recalls, or other corrective measures.

43. In connection with an FSCA, manufacturers may issue a Field Safety Notice ("FSN") to affected customers, healthcare organisations and users. FSNs are communications intended to notify users of identified safety issues and to provide instructions concerning any corrective actions required. The MHRA reviews and oversees such notices as part of its post-market surveillance and vigilance functions.

44. The MHRA may also issue Device Safety Information ("DSI"), Medical Device Alerts ("MDAs"), or other safety communications to healthcare providers and relevant stakeholders where it considers that action or heightened awareness is required in relation to a device-related risk. Such communications may contain advice regarding the safe use of devices, enhanced monitoring, restrictions on use, recommended mitigations, or actions to be taken by healthcare organisations.

45. In appropriate circumstances, the MHRA may undertake further regulatory interventions, including requiring manufacturers to provide additional information, imposing conditions, suspending or restricting the supply of devices, conducting inspections, or taking enforcement action where there is non-compliance with applicable regulatory requirements.

46. The MHRA's role in this regard is directed principally toward product safety regulation and risk mitigation at a national level. Healthcare providers, including NHS bodies and

independent providers, remain responsible for implementing relevant safety actions locally, including reviewing and responding to FSNs, DSIs, MDAs and other safety communications, and for ensuring that appropriate clinical governance and patient safety processes are in place within their organisations.

Yellow Card Scheme

47. Voluntary reporting routes are available through the MHRA's Yellow Card Scheme for healthcare professionals and the general public. If a healthcare professional identifies a fault or concern or experiences an incident with a medical device, they can report this through the Yellow Card website. The Yellow Card reporting system asks the reporter to detail if they are a patient, relation of a patient or a healthcare professional. Further details are then requested, including age, weight, height, ethnicity, pregnancy, past medical history and co-morbidities alongside details of the medical device and the incident or issue.

48. The Yellow Card Scheme collects and monitors this information on suspected safety concerns or incidents involving vaccines, medicines, medical devices, and e-cigarettes. The scheme also collects suspected safety concerns involving defective (not of an acceptable quality), falsified or fake healthcare products.

Vigilance reporting

49. In addition to reports received through the Yellow Card Scheme, manufacturers are subject to separate obligations to report certain incidents involving their medical devices to the MHRA. These obligations form part of the Medical Device Vigilance System, which is the regulatory framework through which the MHRA monitors the safety and performance of medical devices after they have been placed on the market. The purpose of the vigilance system is to facilitate the identification, investigation and assessment of device-related safety issues and to support the implementation of any necessary corrective or regulatory action.

50. Manufacturers are required to report incidents meeting the applicable vigilance criteria, as set out in relevant MHRA guidance and, at the material time, the European Commission guidance on medical device vigilance. In broad terms, the Medical Device Vigilance System is intended to facilitate the reporting and investigation of incidents involving medical devices that have resulted in, or could have resulted in, death or serious deterioration in a patient's, user's or other person's state of health.

51. An event may be reportable where it involves an actual or suspected malfunction, deterioration in performance, inadequacy in the device's design, manufacture, labelling or instructions for use, and there is a reasonable possibility that the event caused, or could have caused, a serious adverse outcome.

52. Accordingly, a reportable event is not limited to incidents where serious harm has in fact occurred. Events which reveal a device-related failure or deficiency that had the potential to result in death, or serious injury may also fall within the scope of the vigilance reporting regime and warrant assessment by the MHRA.

53. Manufacturers also can issue Field Safety Notices ("FSNs") to inform their customers about corrective actions needed to address safety issues with medical devices. Any FSN would be posted on the MHRA website.

Oxevision

54. The Oxevision platform, manufactured by Oxehealth Ltd, is a video-based monitoring technology that comprises of different functions and software modules, some of which fall within the definition of a regulated medical device for the purposes of MHRA regulation. The functions of the Oxevision platform which fall into the definition of a medical device include; contactless physiological monitoring, in particular the measurement of pulse rate and respiration rate through infrared and camera-based sensing technology (Oxevision Vital Signs). The Oxevision Vital Signs module is qualified as a medical device and is classified as a Class IIa software medical device. Subsequent to the MHRA enquiries on the Oxevision platform and the Oxevision Vital Signs reported herein, Oxehealth Ltd has obtained regulatory certification in relation to the Oxevision Sleep System, a Class IIa medical device software under EU MDR 2017/745, which now also forms part of the Oxevision platform. The MHRA has not undertaken any review or investigation of the Oxevision Sleep software medical device.

55. By contrast, other functions within the Oxevision platform operate primarily as observation, workflow, monitoring, alerting or administrative tools and may not themselves constitute regulated medical devices. Based on the material publicly available, these functions appear to include:

    a. digital observation and record-keeping tools;
    b. room occupancy, location or movement monitoring;

c. activity-based alerts and notifications;
d. anonymised or blurred visual monitoring functions;
e. reporting, analytics and ward management tools; and
f. other operational or workflow-support functions intended to assist clinical staff.

56. The fact that certain components of a broader platform (hardware and software) are certified medical devices does not necessarily mean that all functions within the same platform (or the installed hardware itself) are themselves certified as medical devices and regulated by the MHRA. Whether a particular function constitutes a medical device depends upon its intended purpose and whether it meets the applicable statutory definition under medical devices legislation. Products classified as medical devices must demonstrate they meet the requirements of UK medical devices regulations. The intended purpose statement should provide the reader with an understanding of the appropriate “state of the art”, product risk level, and the evidence required to demonstrate the safety of the product.

57. I have been asked to describe the MHRA’s awareness, if any, of concerns raised about the Oxevision platform, including the Oxevision Sleep Device and Oxevision Vital Signs and its use on mental health wards, including concerns relating to safety, accuracy, reliability, or real-world use.

58. The MHRA has received four reports through its Yellow Card Scheme regarding the Oxevision Vital Signs and Sleep System [EXHIBIT 19-22]. The Yellow Card reports comprise a series of Manufacturer Incident Reports submitted by Oxehealth to the MHRA concerning identified anomalies in the Vital Signs software's pulse rate measurements. The reports relate to isolated incidents where the software generated inaccurate pulse rate readings, including due to breathing-rate harmonics, instability in infrared illuminator power supplies, and site-specific environmental factors affecting signal quality. In each case, the issues were identified through Oxehealth’s post-market surveillance and monitoring processes, investigated by the company, reported to the regulator in accordance with applicable vigilance requirements, and assessed as having caused no reported patient harm.

59. In November 2017, following a review of submitted documents, the MHRA raised a “no objection” to an application from Oxehealth Ltd to conduct a Clinical Investigation involving vital signs measurement software (Oxecam) which had been developed by the

company [EXHIBIT REF 15, 16, 16a,16b,16c and 17]. Prior to April 2021, when the MHRA were first made aware of the Oxevision platform by NHS England and NHS Improvement (NHSE&I), there had been no safety concerns relating to the technology reported to the Agency. The MHRA's enquiries into Oxevision were focused on the Oxevision Vital Signs module and the regulatory status of the Oxevision Activity Tracker module. At the time, the Oxevision Sleep feature was not part of the platform and was not part of the MHRA enquiries. The MHRA's enquiries were conducted alongside enquiries being raised by NHSE&I. Some of those enquiries were made under the regulatory remit and some aspects, which related to the non-medical device aspects (including the installation of the equipment), were primarily the interest of NHSE&I.

60. On the 26 April 2021, the Patient Safety Team at NHSE&I contacted the MHRA Devices Patient Safety Manager with a request for the MHRA to provide the Instructions For Use (IFU) for the Oxevision product. Instructions for Use are a document supplied by the manufacturer that provides the information necessary for the safe, effective, and intended use of a medical device, including its indications, contraindications, warnings, operating procedures, maintenance requirements, and other information needed by the intended user. They stated: "*We have a few concerns and would like to understand more about what this is licensed for and what is stated in the IFU, without contacting the manufacturer directly."* Following some initial clarifications, during which the MHRA confirmed to NHSE&I that medical devices are regulated differently to medicines and that the MHRA does not hold copies of instructions for use for individual products [EXHIBIT REF 1], the MHRA contacted the manufacturer to obtain the *Instructions for Use* on behalf of NHSE&I. In response, the company advised the MHRA that : "*Oxevision platform itself is not a medical device as the platform and other products did not have a medical purpose or medical device classification of their own according to the Medical Device Directive and Medical Device Regulation classification rules. However, the Oxevision platform does host other Oxehealth software products as well including the Vital Signs product which is a Class IIa software medical device that has been cleared for placing on the market under the Medical Devices Directive 93/42/EEC"* [EXHIBIT REF 2].

61. The MHRA passed the IFUs on to NHSE&I.

62. In correspondence dated 27 May 2021, NHSE&I provided some high-level concerns to the MHRA about the Oxevision platform, particularly when deployed in mental health care settings. NHSE&I were concerned that there was no apparent information on the

safe fitting of monitors to avoid ligature risk when linked to the medical device. NHSE&I stated to the MHRA that whilst Oxehealth Ltd appears to undertake fitting with its own engineers, there was still a need for clear instructions since trusts would have responsibilities for ensuring these were safe, even if they had not installed them. The NHSE&I added that they were aware of a reported incident of unsafe fitting. The NHSE&I also stated that they considered there to be a risk that the equipment's capabilities could be misunderstood by staff, potentially leading to patient harm. [EXHIBIT REF 1].

63. The MHRA Software Team sent initial questions to Oxehealth Ltd on 26 May 2021 and received answers from the company on 27 May 2021. The MHRA continued to review information about both the platform and the Vital Signs medical device component. However, because of the complexity that some aspects of the product were a medical device, whilst other aspects of the platform were out with the MHRA's remit, it was necessary to establish those aspects for the MHRA to address and those which remained the remit of the NHSE&I. The NHSE&I had prepared an internal briefing document in May 2021 which was redacted and shared with the MHRA on 1 September 2021 [EXHIBIT REF 3]. A briefing was provided for an MHRA internal safety reporting meeting on 29 September 2021 [EXHIBIT REF 4] which set out the proposed lines of enquiry for further investigation and to consult with other teams who may have had an interest. The MHRA and the NHSE&I met with Oxehealth Ltd on 27 October 2021 to receive a detailed briefing on the Oxevision platform and the Oxevision Vital Signs module. The MHRA continued to review the materials provided and raised further questions with the company on 15 November 2021 including on the algorithm for the Vital Signs module as well as including questions raised by NHSE&I's ongoing interests. The responses were provided to the MHRA on 20 December 2021. In response to these, further questions were asked on 9 February 2022 which were answered on 2 March 2022 [EXHIBIT REF 5 and REF 6].

64. In particular, the post-market engagement between the MHRA and Oxehealth Ltd addressed:

    a. **Marketing and website claims** NHSE&I and the MHRA reviewed the claims that were made by the company relating to "*preventing self-harm*" and the provision of "*advanced alerts"***.** The claims made were not clearly linked to either the medical device (Vital Signs) or the non-medical device platform and other software modules. The NHSE&I were primarily concerned that these claims may cause staff and patients to incorrectly believe the system would automatically alert staff to

deterioration and/or self-harm which could create an unsafe reliance on the Oxevision system. From an MHRA perspective, the Oxehealth Ltd website and promotional materials for Oxevision were reviewed, specifically the inclusion of the term "*reducing self-harm*" under the system's "Application". It was considered by the MHRA that this statement could be interpreted as a statement of intended use and that the system can reduce incidents of self-harm. Given the nature of this statement and the use of the platform and Vital Signs module in vulnerable patient populations, this was considered by the MHRA likely to constitute a medical purpose.

To be able to make claims relating to a medical purpose, the manufacturer must be able to support it with relevant evidence. To clarify the regulatory position, the MHRA Software Team consulted with relevant MHRA teams, including the Devices Compliance Unit [EXHIBIT REF 7]. These internal discussions focused on how Oxehealth Ltd was promoting the system, including website statements and percentage-based claims such as "*staff reported that Oxevision enabled them to prevent incidents of self-harm from occurring*".

The company had included such claims in promotional materials and the MHRA considered that these could imply a clinical benefit and therefore fall within the scope of the Medical Devices Regulations (2002). The MHRA concluded that, on that basis, clinical evidence would be required to substantiate the claims, and, without such evidence, the claim should not be made. This regulatory interpretation was communicated to Oxehealth Ltd in correspondence on 9 February 2022. In response, Oxehealth Ltd acknowledged the risk of misinterpretation and amended the relevant content on their website on 23 February 2022 and confirmed in correspondence to the MHRA on 2 March 2022 that changes to the website, promotion and standard training materials had also been made [EXHIBIT REF 6]. Additional correspondence dated 27 May 2022 confirms that further changes to the website had been made in response to MHRA's view on this matter [EXHIBIT REF 8]. The MHRA also raised this technology with the Software Expert Advisory Group (SEAG) in June 2022. The SEAG provided comments in support of the actions taken by the MHRA [EXHIBIT REF 18].

b. **Fitting and installation of Oxevision housing equipment:** Whilst not clearly sitting within the MHRA's regulatory remit, the MHRA worked with NHSE&I on matters raised by NHSE&I concerning fitting instructions. The company confirmed that the installation responsibilities are split between the customer and Oxehealth Ltd.

Oxehealth Ltd stated to the MHRA that the housing for the equipment is not installed by themselves and this is provided to the customer, who then install this using their own staff or subcontractors. Oxehealth Ltd provide an installation plan to the customer, including guidance for housing installation. Oxehealth Ltd subsequently install the camera and illuminator into the housing according to an internal installation guide. Oxehealth Ltd requires a customer representative to sign a hardware acceptance form following completion of installation, to ensure that they have inspected the installation and have assessed it for safety according to all of their own requirements for their environment. The NHSE&I considered that the fitting guidance needed to be more robust regarding ligature risk and provided recommendations to the company for improvement which was included in correspondence sent by the MHRA. Oxehealth Ltd agreed to incorporate suggestions into its user guidance [EXHIBIT REF 6].

c. **Reporting and management of incidents:** In response to the MHRA's enquiries, the company provided details of complaints that had been received about the Oxevision Vital Signs device. The MHRA reviewed those cases and the MHRA considered that one report was identified as a potentially reportable event under the Medical Device Vigilance System. Further information on the Medical Device Vigilance System can be found at paragraphs 54-58. The Software Team sought advice from an MHRA clinical advisor, who advised that the incident was likely to meet the criteria for a vigilance report [EXHIBIT REF 9]. On further enquiry by the MHRA, the company advised that during their investigation of this particular case, they had implemented a software update. However, they had not considered the event as reportable to the MHRA under the vigilance system and so the Agency was not aware. The company were advised that it was the opinion of the MHRA that this report did meet the requirement for the submission of a Manufacturer Incident Report form. The company acknowledged the MHRA view and subsequently issued a Field Safety Corrective Action (FSCA) and a Field Safety Notice. The FSN was published Field Safety Notices: 09 to 13 May 2022 - GOV.UK [EXHIBIT REF 10]. As part of the FSCA, the corrective action implemented was a software update. The MHRA acknowledged the company's rationale for the initial absence of an FSN however, in accordance with established procedures, advised that an FSN should still be issued to all users with an acknowledgment form. The MHRA confirmed that it was acceptable for the FSN to state that the software update had already been implemented and that no further action was required by users. On 1st of April 2022, the manufacturer confirmed in writing to the MHRA that it had undertaken a review of

its vigilance processes with the Notified Body to gain an understanding of the differing interpretation, and that they had updated their procedures.

d. **Data privacy:** The NHSE&I had some concerns about data retention practices and issues around informed consent. Data privacy had been raised during internal MHRA discussions. However, as data protection falls outside of the MHRA's regulatory remit, the MHRA Software Team notified the Information Commissioner's Office (ICO), and an introductory meeting was held with the ICO. The MHRA Software Team provided an outline of the basis for the technology to the ICO. After this meeting, the MHRA had no further engagement with the ICO on the Oxevision product [EXHIBIT REF 11 email].

e. Oxevision Activity Tracker: The MHRA reviewed the Activity Tracker software component. Oxehealth confirmed that the Activity Tracker detects activity, posture, presence and location and can operate independently of the Vital Signs module. Based on the information provided by the company, following internal discussions with the MHRA Borderlines team, the MHRA concluded that the Activity Tracker was not likely to qualify as a medical device, primarily because the alerts are not intended for a medical purpose Ref 12. During the course of the MHRA review (and before a decision on the Agency's interpretation had been communicated to the company), Oxehealth Ltd had independently concluded that the Activity Tracker software did qualify as a medical device, had self-declared the product as a Class I medical device and had registered the product with the MHRA. However, upon receipt of the regulatory opinion provided by the MHRA, the company decided to remove the Declaration of Conformity and de-register the device with the MHRA [EXHIBIT REF 13].

f. In January 2024, the MHRA were informed by NHS England of a report of a case in which a patient died whilst inside a room fitted with the Oxevision platform [EXHIBIT REF 14]. NHS England forwarded the case report to the MHRA 'for information' given our previous engagement on the Oxevision platform. The report did not make any reference to the use of the Oxevision Vital Signs medical device. The case report did reference the Activity Tracker report (which is not a medical device) and is therefore outside of the medical device vigilance system and there is no requirement for the manufacturer to report the case to the MHRA. Given the Oxevision Activity Tracker is not a medical device, and given NHS England were already aware of the incident, the MHRA took no further action.

Statement of Truth

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

Signed:

[I/S]

Dated: 01.09.26