

SECOND WITNESS STATEMENT

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Response to request for further information concerning the deployment of new technologies in healthcare settings and the Oxevision system dated 27 August 2026

MHRA's statutory role

1. I have been asked to provide further clarification concerning the respective responsibilities of the MHRA, Approved Bodies, Notified Bodies, and healthcare providers in relation to medical devices such as Oxevision Vital Signs.
2. The MHRA is an executive agency of the Department of Health and Social Care (DHSC). The MHRA is responsible for regulating medical devices on the UK market and discharging the functions of the Secretary of State under the Medical Devices Regulations 2002.
3. The Medicines and Medical Devices Act 2021 ("MMD Act") granted the MHRA enhanced enforcement powers, including the power to issue compliance notices, suspension notices, safety notices and information notices in relation to non-compliance with the Medical Devices Regulations 2002.
4. For completeness, I clarify paragraph 3 of my First Witness Statement. While the Medical Devices Regulations 2002 are no longer recognised as "safety regulations" for the purposes of the Consumer Protection Act 1987, they continue to be recognised as safety regulations for the purposes of section 12 of that Act pursuant to regulation 3 of the Medicines and Medical Devices Act 2021 (Commencement No. 1 and Transitional, and Savings Provisions) Regulations 2021.

5. The MHRA regulates medical devices within its statutory remit under the Medical Devices Regulations 2002. Specifically, the MHRA's responsibilities include;
- a. Setting and maintaining the regulatory framework governing medical devices;
 - b. Reviewing and assessing clinical investigation applications before studies commence;
 - c. Assessing allegations of non-compliance;
 - d. Monitoring post-market safety through vigilance systems and with the MHRA's yellow card reporting scheme and manufacturer incident reporting;
 - e. Reviewing field safety corrective actions and field safety notices;
 - f. Taking enforcement action where necessary;
 - g. Designating and monitoring UK approved bodies.

6. Since January 2001, The UK Medical Devices Regulations 2002 have required all medical devices, regardless of assurance marking, to be registered with the MHRA before being placed on the Great Britain (GB) market. The MHRA maintains this registration database for information and traceability purposes. Registration on the MHRA's list of medical devices placed on the GB market does not constitute an assessment by the MHRA nor certification, approval or endorsement of a device.

7. Higher risk devices, including Class IIa devices, such as Oxevision Vital Signs, require conformity assessment to the UK MDR 2002 by a third-party UK Approved Body or conformity assessment to EU regulations by a third-party EU Notified Body before being placed on the market. It is the role of Notified Bodies (under the EU regulatory framework) and Approved Bodies (under the Great Britain regulatory framework) to assess whether a medical device complies with the applicable regulatory requirements before issuing the relevant conformity assessment certification. The MHRA is responsible for designating and monitoring the performance of UK Approved Bodies.

8. Once a Class IIa (such as Oxevision Vital Signs) or higher risk device has been issued with a conformity assessment certificate by a UK Approved Body or EU Notified Body, its manufacturer can apply a conformity assessment mark (UKCA or CE) to the product and packaging. Conformity markings signify that a medical device meets specific safety and performance requirements, providing assurance to consumers and facilitating market access. Different conformity marks (CE or UKCA) are used depending on the regulations that the device complies with i.e. EU Regulations or UK Regulations respectively. Great Britain also currently accepts CE-marked medical devices on the Great Britain market under EU Exit transitional arrangements.
9. The MHRA does not undertake conformity assessments of individual devices before they are placed on the market and does not certify devices for CE or UKCA marking. Rather, the MHRA is responsible for oversight of the regulatory framework that devices are assessed to, designation and monitoring of Approved Bodies, monitoring post-market safety and performance, analysis of device vigilance data, investigations into potential non-compliance, and regulatory enforcement where appropriate.
10. The MHRA's role is also distinct from that of healthcare providers. The MHRA does not determine whether a technology should be procured, deployed, or relied upon within a particular clinical environment. Healthcare providers retain responsibility for procurement decisions, implementation, clinical governance arrangements, local patient safety assessments, staff training, operational risk management and determining whether a technology is suitable for deployment in a particular healthcare setting.
11. Accordingly, conformity marking does not in itself constitute a recommendation that a device should be deployed in any particular environment or patient population.

12. In relation to Oxevision Vital Signs specifically, the MHRA's engagement focused on regulatory questions concerning:
- a. The classification of the vital signs module as a Class IIa medical device;
 - b. Marketing claims that could imply a medical purpose;
 - c. Vigilance reporting obligations and incident reporting;
 - d. The regulatory status of the activity tracker module.

Conformity Assessment

13. I have also been asked to provide further information regarding the conformity assessment applicable to Oxevision Vital Signs.
14. Oxevision Vital Signs is a Class IIa software medical device. As such, it requires conformity assessment by an Approved Body or Notified Body before being placed on the market. The conformity assessment applicable to Oxevision Vital Signs was undertaken by the British Standards Institution ("BSI"), acting in its capacity as the relevant conformity assessment body. BSI is an Approved Body under the UK MDR 2002.
15. BSI's examination of the quality assurance system was under the requirements of Part II of the Medical Devices Regulation 2002, Annex II excluding Section 4 [as modified by Part II of the Schedule 2A of the Medical Devices Regulation 2002]. The quality assurance system was assessed to have met the requirements of the regulation. The Section 4 certificate was first issued by BSI on 05-09-2023.
16. The purpose of conformity assessment is to determine whether a device satisfies the applicable regulatory requirements relating to safety, performance, and quality before certification may be issued. The MHRA does not undertake

conformity assessments of individual devices before they are placed on the market and does not certify devices for CE or UKCA marking.

17. Conformity assessment includes review of the manufacturer's:

- a. clinical evaluation;
- b. technical documentation;
- c. quality management systems;
- d. risk management procedures;
- e. post-market surveillance arrangements
- f. assessment against the applicable essential requirements relating to safety and performance;
- g. And overall conformity with medical device legislation for certification.

Potential patient harms

18. Potential patient harms associated with the device are assessed both pre- and post-market through clinical evaluation of compliance with essential safety requirements, and post-market surveillance requirements. The applicable requirements provide that devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or safety of patients, users, or other persons, and that any risks associated with their use are acceptable when weighed against the benefits to the patient.

19. Once a medical device has been placed on the Great Britain market, the manufacturer is required to follow risk proportionate post-market surveillance regulations. These require it to report to the MHRA when serious incidents occur in Great Britain that involve their device and take appropriate safety action and to provide periodic safety updates reports to Approved Body for higher risk devices. Since new regulations came into effect in June 2025, the Medical

Devices (Post-market Surveillance Requirements) (Amendment) (Great Britain) Regulations 2024, 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.

Intended purpose and clinical environment

20. The intended purpose of the device is central to the conformity assessment process. The intended purpose assists in determining device classification, the applicable regulatory requirements and the nature of the supporting evidence required to demonstrate safety and performance.
21. Under the UK MDR 2002 Regulation 2(1), the definition of 'Intended Purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or promotional materials.
22. As explained in my first witness statement, whether a product constitutes a medical device depends upon its intended purpose and whether it meets the applicable statutory definition under the Medical Devices Regulations 2002. Oxevision Vital Signs falls within that definition and is classified as a Class IIa software medical device.
23. 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.

24. 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.

25. 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.

Clinical or peer-reviewed evidence

26. Clinical evaluation and supporting evidence such as scientific literature form an important part of conformity assessment. Manufactures are required to provide evidence demonstrating that their medical device satisfies the applicable requirements relating to safety and performance. Depending upon the nature and classification of the device, such evidence may include data from clinical studies (termed clinical investigations under UK regulations), published scientific literature and other relevant clinical data.

27. Further information on the clinical or peer-reviewed evidence supporting the safety and performance including any material limitations or uncertainties in that evidence is described in [Directive - 93/42 - EN - medical device directive - EUR-Lex](#), Annex X;

28. The assessment of clinical evidence is undertaken by the Approved Body or Notified Body as part of the conformity assessment process, not by the MHRA.

In the case of a Class IIa software medical device such as Oxevision Vital Signs, that assessment includes consideration of clinical evaluation evidence, alongside technical documentation, quality-management systems, risk-management procedures, post-market surveillance arrangements and compliance with the applicable regulatory requirements relating to safety and performance.

29. However, conformity assessment including the assessment of data from clinical studies does not determine whether a technology should be deployed within a particular clinical environment. Deployment within a particular environment is not a decision taken by the MHRA. And pre-market assessment of clinical data as part of the conformity assessment process does not remove the responsibility of healthcare providers to undertake their own procurement, governance, clinical safety and risk assessment processes.

30. 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.

31. The MHRA's product regulation is separate from deployment decisions. NHS Trusts and other healthcare providers retain primary responsibility for assessing risks arising from local installation, deployment, clinical context and operational use. Healthcare providers remain responsible for procurement decisions, clinical governance, local risk assessments, patient-safety management, implementation, staff training and operational risks.

Respective Responsibilities

32. Depending on the device's risk classification, the pre-market conformity assessment may be undertaken by the manufacturer to self-certify a device (for General Class I devices only) or must be undertaken by an independent Approved Body, or by a Notified Body for Class I devices that are sterile or have a measurement function and Class IIa, Class IIb and Class III devices. Approved Bodies and Notified Bodies also undertake ongoing surveillance of a manufacturer throughout the lifecycle of the conformity certificate. This includes annual surveillance audits as well as reviewing manufacturers' post-market surveillance reports.
33. Manufacturers are responsible for preparing the technical documentation that demonstrates that its products conform to the requirements of the UK MDR 2002 and keeping this documentation up to date. Where a manufacturer is based outside of the UK, a UK Responsible Person registered with the MHRA should have access to this up-to-date technical documentation. Manufacturers must keep the documentation for a period ending at least 5 years after the last products have been manufactured. The MHRA can ask to see the documentation at any time. Manufacturers are also responsible for ensuring that post-market surveillance requirements are met, including reporting of serious incidents to the MHRA.
34. Once a medical device has been placed on the GB market, the manufacturer is required to submit vigilance reports to the MHRA when serious incidents occur in Great Britain 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.

35. The MHRA's role is in setting the overall regulatory framework that devices and their manufacturer must meet to access the Great Britain market. The MHRA then has specific activities within this framework. These include assessment of proposed clinical investigations, designation and monitoring of Approved Bodies, and post-market surveillance, and taking enforcement when required.
36. Overall responsibility for complying with the pre- and post-market regulatory requirements rests with the manufacturer, but other bodies (i.e. Approved Bodies) also play a role.
37. However, conformity assessment does not determine whether a technology should be deployed within a specific clinical environment. Considerations relating to local implementation, installation, staff training, operational procedures and clinical governance remain matters for healthcare providers.

Clinical Investigations

38. Clinical investigations are clinical studies of devices. The MHRA assesses clinical investigation applications and can object to a study being undertaken if appropriate. The data obtained by a clinical investigation is assessed by the Approved/Notified Bodies as part of the conformity assessment.
39. I have been asked to provide further information regarding the November 2017 clinical investigation involving Oxehealth's Oxecam technology and the MHRA's role in relation to that investigation.
40. The purpose of the November 2017 clinical investigation was to evaluate the clinical performance and accuracy of the Oxecam non-contact monitoring system for measuring heart rate and breathing rate. The investigation was intended to generate evidence on the accuracy and usability of Oxecam's non-contact measurement of pulse and respiratory rate.

41. The study was described as a feasibility study and was designed to compare measurements obtained using Oxecam against those from a reference contact monitoring device.
42. The primary objectives were to assess the accuracy of heart rate and breathing rate measurements made by users with the non-contact monitoring system. Secondary objectives included assessing the frequency with which heart rate and breathing rate measurements could be successfully obtained in normal circumstances and during a number of specific activities. Tertiary objectives included assessing the accuracy of heart rate and breathing rate measurements made automatically by the non-contact monitoring system without user interaction.
43. The primary endpoint was the Root Mean Squared error between measurements of heart rate and breathing rate made by a trained user using the non-contact monitoring system and measurements made using a standard contact monitoring device. The secondary endpoint was the ratio of successful observations obtained by the user to the total number of observation attempts made. The tertiary endpoint was the Root Mean Squared error between measurements of heart rate and breathing rate made by the non-contact monitoring system using a number of cameras without user interaction and measurements made using a standard contact monitoring device.
44. In November 2017, following review of the documentation submitted by Oxehealth Ltd, the MHRA issued a "no objection" determination on the 4th October 2017 in relation to the proposed clinical investigation involving the Oxecam vital signs measurement software. This can be found in [EXHIBIT 23].
45. The MHRA completed a pre-study regulatory review of the proposed clinical investigation. Clinical, technical, statistical, and software assessments were undertaken, and a conditional no-objection determination was issued subject to

specified software documentation being provided. This letter was issued on 17th November 2017 and can be found [EXHIBIT 24]. The assessor documentation relating to clinical, technical, statistical and software assessments can be found in [EXHIBIT 25] with A) and B) referring to clinical assessment, C) referring to technical and electronic, D) referring to statistics and E) referring to software.

46. The MHRA did not undertake a conformity assessment of the device, did not certify the device for placement on the market, and did not rely upon the findings of the investigation as part of any conformity assessment process because this was not our role. Rather, the MHRA's role was limited to regulatory oversight of the proposed clinical investigation and assessment of compliance with the applicable regulatory requirements. Documentation was provided in [EXHIBIT REF 15, 16, 16a, 16b, 16c and 17] in the first witness statement. We have also provided the original application documents received by the MHRA on 9th August 2017 in this response [EXHIBIT 26 an index is included in 26A) with exhibits provided for A-V].

47. The purpose of the MHRA's review was to assess the proposed clinical investigation in accordance with the applicable regulatory framework and determine whether there were grounds upon which the investigation should not proceed. The MHRA's review was distinct from any conformity assessment process. A summary of the MHRA Final Review can be found in [EXHIBIT 27].

48. The MHRA has disclosed the application documents, assessment correspondence, review reports and outcome letters held by the Agency relating to the matters described above.

49. The MHRA does not hold the final clinical investigation report on file. Under Regulation 16(10) of the Medical Devices Regulations 2002, responsibility for retaining the final study report rests with the manufacturer. The MHRA reviews clinical investigations at the pre-market stage, which will contribute to the

technical file. The full technical and clinical evaluation file for a class II product will then go through an Approved Body for review and certification.

50. The Inquiry should note that the MHRA's "no objection" related specifically to the proposed clinical investigation and should not be understood as an approval or endorsement of the Oxecam software itself. A clinical investigation is undertaken to generate clinical evidence regarding a medical device. The MHRA's role is to consider whether there were grounds to object to a proposed investigation proceeding on the basis of the information submitted. A Research Ethics Committee (REC) will also provide an ethical opinion. The MHRA does not necessarily undertake an assessment of the results of a clinical investigation once completed and responsibility for conducting the investigation and analysing results rests primarily with the sponsor. The 2017 decision did not determine the regulatory status or safety of Oxehealth's Oxecam or other products. This decision related only to MHRA's regulatory opinion on the clinical investigation itself taking place.

Emerging and Innovative Technologies

51. I have been asked to explain the MHRA's role in identifying and monitoring emerging and innovative technologies, and whether Oxevision or vision-based monitoring technologies were subject to any additional assessment or scrutiny as a result of their innovative nature.

52. The MHRA has an important role in supporting the safe and more rapid development of innovative and emerging medical technologies. The MHRA delivers this through a range of regulatory tools and initiatives, including regulatory sandboxes and the development of early access pathways. These initiatives provide early regulatory support to developers whilst maintaining appropriate safeguards, clear eligibility criteria, and ongoing oversight of

products under controlled conditions. Participation does not alter the applicable regulatory requirements, and products must continue to meet the relevant safety and performance standards before being placed on the Great Britain market. Oxevision was not part of any such initiative and was assessed through the standard regulatory processes applicable to medical devices.

53. The assessment of whether a product falls within the scope of MHRA's regulatory remit is determined by reference to the intended purpose of the product and whether it meets the statutory definition of a medical device, rather than by whether a product is considered novel or innovative. Under Regulation 2(1) UK Medical Devices Regulations 2002, consistent with Article 1(2)(a) of Directive 93/42/EEC Directive - 93/42 - EN - medical device directive - EUR-Lex, whether a product is a medical device depends on its intended medical purpose, including diagnosis, prevention, monitoring, treatment or alleviation of disease. The novelty of the underlying technology is not determinative of medical device status.

54. The MHRA did not identify Oxevision as an "emerging" or "innovative" technology requiring a separate regulatory assessment process. The MHRA engaged with Oxevision because certain functions of the platform, including Oxevision Vital Signs, fell within the definition of a medical device and were therefore subject to the Medical Devices Regulatory Framework.

55. The MHRA's regulatory considerations were determined by:

- a. whether a particular function met the legal definition of a medical device,
- b. the intended purpose claimed by the manufacturer,
- c. the applicable device classification and conformity assessment requirements,
- d. and post-market surveillance and vigilance obligations.

56. The fact that a technology is new, incorporates software, uses camera-based monitoring, or utilises novel methods of monitoring does not in itself give rise to

a separate regulatory pathway. Rather, the applicable regulatory requirements are determined by the intended purpose of the product and the risks associated with that intended purpose.

57. The deployment of a technology within a mental health inpatient environment does not alter the MHRA's statutory role, or the criteria used to determine whether a product qualifies as a medical device. The deployment setting, degree of clinical risk and whether a technology is novel, complex or integrated into wider clinical systems are matters that may be relevant to healthcare providers' own procurement, governance, clinical safety and risk-assessment processes.
58. The MHRA's approach to identifying emerging safety concerns associated with new technologies includes review of information received through the Yellow Card Scheme, manufacturer vigilance reporting, post-market surveillance activity, engagement with healthcare organisations, manufacturers and other regulators, together with assessment of information from safety investigations and other sources. The MHRA also undertakes routine trend analysis across groups of products to identify emerging safety concerns and support regulatory action where appropriate.
59. The [MDR IVDR guidance Print 13.pdf](#) details the MHRA guidance on medical device qualification, classification, vigilance reporting and post-market safety. The [Medical devices: post-market surveillance - GOV.UK](#) provides more information on the Medical Device Vigilance System.
60. The MHRA's role in relation to emerging technologies is to support the safe development of innovation whilst ensuring that appropriate regulatory standards are maintained. As noted, this includes the use of regulatory initiatives such as regulatory sandboxes and the development of early access pathways. The Agency applies the medical devices regulatory framework to products within its remit, monitors safety and performance once products are in use, and takes

regulatory action where appropriate. The novelty of a technology does not, in itself, alter the regulatory requirements that apply to it.

Monitoring and Identification of Emerging Safety Concerns

61. I have been asked to explain how the MHRA identifies, monitors, and responds to emerging safety risks associated with medical devices following their placement on the market, including risks that arise through real-world deployment and use.

62. The MHRA has a number of established mechanisms through which it identifies, assesses and responds to emerging safety risks associated with new technologies. These include the Yellow Card Scheme, the Medical Device Vigilance System, review of Manufacturer Incident Reports, assessment of Field Safety Corrective Actions and Field Safety Notices, post-market surveillance activities, and where appropriate, the use of regulatory and enforcement powers.

63. While the MHRA plays a role in monitoring device safety, the primary responsibility for post-market surveillance and reporting rests with the medical device manufacturer, as a mandatory requirement under the Medical Devices Regulations 2002. Manufacturers are required to monitor the performance and safety of their devices once they are in use and to report relevant safety concerns to the MHRA through the appropriate vigilance and post-market surveillance processes.

64. The processe(s) for identifying, assessing, and responding to emerging safety risks can be influenced by factors such as the availability and quality of the related information, reporting of incidents, identifying/detecting indirect harms, real-world deployment and use, and the need for coordination across multiple organisations. Recent strengthening of post-market surveillance requirements has been intended to improve the detection of emerging risks and support more

effective regulatory responses. More detail can be found at [Medical devices: post-market surveillance - GOV.UK.](#)

65. Safety signals may arise from a variety of sources, including both proactive and spontaneous reporting. Voluntary reports may be submitted by patients, carers and healthcare professionals through the Yellow Card Scheme. Other potential sources of safety information include academic publications and research, device registries, spontaneous enquiries, Freedom of Information requests, online media, feedback from national stakeholders such as NHS England, devolved administrations, NHS Supply Chain, Medical Device Safety Officers, clinical and professional bodies, information received from international regulators and other surveillance activities.

66. Following identification of a potential safety signal, the MHRA may undertake a benefit-risk evaluation to determine whether further investigation or regulatory action is required.

67. The MHRA also undertakes routine trend analysis across groups of products to identify emerging safety concerns and support regulatory action where appropriate.

Yellow Card Report

68. Voluntary reporting routes for reporting are available through the MHRA's Yellow Card Scheme for healthcare professionals and the general public. Where a concern, fault, or incident involving a medical device is identified, a report may be submitted through the Yellow Card reporting system.

69. 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. 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. This information received contributes to the MHRA's wider surveillance and signal-detection activities and may assist in identifying previously unrecognised safety concerns or trends requiring further assessment.

Medical Device Vigilance System

70. 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.
71. 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.
72. 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.

Field Safety Corrective Action (FSCA) and Field Safety Notice (FSN) processes:

73. One form of regulatory action is the issuance or oversight of Field Safety Corrective Actions (“FSCAs”) undertaken by manufacturers.
74. 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.
75. 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.

Device Safety Communications and Medical Device Alerts

76. 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.

77. 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.

78. 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.

Oxevision:

79. In relation to Oxevision, the MHRA received information from a number of sources, including NHS England, Oxehealth Ltd and Manufacturer Incident Reports submitted through established vigilance reporting mechanisms. The MHRA assessed that information in accordance with its established vigilance and post-market surveillance procedures.

80. As detailed in the first witness statement, the MHRA 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.

81. The MHRA first became aware of broader concerns regarding the Oxevision platform in April 2021 following contact from NHSE&I. Those concerns extended beyond the performance of the regulated medical-device functions and included matters relating to deployment within mental health inpatient settings, fitting and installation arrangements, interpretation of system functionality, marketing claims and wider operational use.

82. The MHRA subsequently undertook a programme of engagement with Oxehealth and NHSE&I to distinguish those matters falling within the Agency's statutory remit from those which remained the responsibility of healthcare providers, NHS organisations or other regulators. This engagement included consideration of the regulatory status of Oxevision Vital Signs, marketing claims that could imply a medical purpose, vigilance-reporting obligations, and the regulatory status of the Activity Tracker software component.

83. The MHRA's ability to identify and respond to safety concerns is necessarily dependent upon information being brought to its attention through established reporting pathways and other regulatory engagement. Where concerns relate to matters falling outside the scope of the medical device regulatory framework, the MHRA may engage with or notify other bodies with relevant responsibilities.

84. Further information regarding the MHRA's engagement with Oxehealth and its consideration of those issues is set out later in this statement.

Regulatory Engagement Concerning Oxevision

85. I have been asked to provide further information concerning the MHRA's engagement with Oxehealth and its consideration of concerns raised regarding Oxevision and Oxevision Vital Signs.

86. As detailed in paragraphs 60-64 of my first witness statement, the MHRA became aware of broader concerns regarding the Oxevision platform and its use

within mental health inpatient settings following engagement with NHS England and NHS Improvement ("NHSE&I") in 2021. The MHRA subsequently undertook a programme of engagement with NHSE&I and Oxehealth which included review of documentation, meetings, correspondence and assessment of issues falling within the Agency's statutory remit as the medical-device regulator. The detailed chronology of that engagement and the underlying documentation have already been disclosed to the Inquiry.

87. The MHRA's engagement focused principally on:

- a. the regulatory status of Oxevision Vital Signs as a Class IIa software medical device
- b. marketing and promotional claims that could imply a medical purpose;
- c. vigilance-reporting obligations and post-market safety matters;
- d. the regulatory status of the Oxevision Activity Tracker software module; and
- e. The distinction between matters falling within the medical-device regulatory framework and matters falling outside the MHRA's statutory remit.

88. The manufacturer remains responsible for demonstrating that regulated medical-device functions satisfy the applicable regulatory requirements and for monitoring their safety and performance throughout the device lifecycle. Manufacturers are also expected to consider foreseeable interactions between regulated and non-regulated components of a wider system and to identify, assess and mitigate risks arising from those interactions through their design, risk-management and post-market surveillance processes.

89. Healthcare providers retain responsibility for assessing risks associated with procurement, installation, implementation, integration into local systems, clinical governance arrangements, staff training, operational procedures and the use of technology within a particular healthcare setting.

Marketing claims

90. During the course of enquiries undertaken jointly with NHS England and NHS Improvement, concerns were raised regarding a number of claims appearing in Oxehealth promotional material and website content, including statements relating to the prevention or reduction of self-harm and references to advanced alerts.

91. As set out in paragraph 64(a) of my first witness statement, the MHRA reviewed claims appearing in Oxehealth's promotional materials and website content, including references to reducing self-harm and the provision of advanced alerts.

92. The MHRA considered whether such claims could imply a medical purpose and therefore bring aspects of the product within the scope of the Medical Devices Regulations 2002.

93. In reviewing these materials, the MHRA considered that certain claims could potentially be interpreted as implying a clinical benefit. The MHRA's view was that claims relating to a medical purpose required appropriate supporting evidence and that, in the absence of such evidence, those claims should not be made.

94. This regulatory interpretation was communicated to Oxehealth. In response, Oxehealth amended relevant website content, promotional materials and training documentation. The MHRA subsequently discussed the matter with its Software Expert Advisory Group, which supported the regulatory position adopted by the Agency.

Fitting and Installation

95. As detailed in paragraph 64(b) of my first witness statement, concerns were raised by NHS England and NHS Improvement regarding the installation and

fitting of Oxevision housing equipment, including concerns regarding potential ligature risks within mental health inpatient settings.

96. The MHRA recognised that issues relating to local installation and deployment sat principally outside its direct statutory remit as the medical device regulator. Nevertheless, the MHRA engaged with Oxehhealth and NHS England and NHS Improvement to better understand the arrangements in place and to support consideration of the concerns raised.

97. Oxehhealth explained that aspects of installation responsibility were shared between the company and the healthcare provider. Oxehhealth provided installation guidance and subsequently installed certain equipment, whilst healthcare providers remained responsible for assessing installations within their own environments and ensuring compliance with local safety requirements.

98. NHSE&I considered that additional information concerning ligature risks would be beneficial. Oxehhealth subsequently agreed to strengthen aspects of its installation guidance and supporting documentation.

Reporting and Management of Incidents

99. As detailed in paragraph 64(c) of my first witness statement, the MHRA reviewed information provided by Oxehhealth concerning complaints and incidents associated with Oxevision Vital Signs.

100. Following review of this material and consultation with an MHRA clinical adviser, the MHRA concluded that one event appeared likely to meet the criteria for reporting under the Medical Device Vigilance System.

101. The MHRA communicated this view to Oxehhealth. Oxehhealth subsequently issued a Manufacturer Incident Report, implemented a software update through a Field Safety Corrective Action and issued a corresponding Field Safety Notice.

102. The MHRA reviewed the manufacturer's actions and accepted that the corrective action had been implemented as required. Oxehhealth subsequently

undertook a review of its vigilance procedures and advised the MHRA that those procedures had been updated.

Data Protection and Privacy Issues

103. As detailed in paragraph 64(d) of my first witness statement, concerns were also raised regarding data retention, consent and information-governance matters. The MHRA considered that these matters fell outside its statutory remit as the medical-device regulator. The MHRA therefore notified the Information Commissioner's Office and held discussions regarding the technology.

104. No further regulatory action was subsequently taken by the MHRA in relation to those matters.

Oxevision Activity Tracker and Oxevision Sleep System

105. The MHRA reviewed the Activity Tracker software component as part of its wider engagement with Oxehealth and NHS England concerning the Oxevision platform.

106. Oxehealth informed the MHRA that the Activity Tracker was capable of detecting activity, posture, presence and location and could operate independently of the Oxevision Vital Signs medical device.

107. Following consideration of the information supplied by the manufacturer and internal consultation within the Agency, including with the MHRA Borderlines team, the MHRA concluded that the Activity Tracker was not likely to qualify as a medical device because its alerts were not intended for a medical purpose.

108. The MHRA's conclusion was based upon the intended purpose of the product. Whether software constitutes a medical device depends upon the purpose for which it is intended to be used, rather than the underlying technology through which it operates.

109. As set out at paragraphs 6 to 9 of my first witness statement, whether a product constitutes a medical device depends upon its intended purpose and whether it falls within the statutory definition set out in Regulation 2 of the Medical Devices Regulations 2002. The MHRA's assessment of the Activity Tracker was undertaken applying those principles.

110. During the course of the MHRA review, and before the Agency had communicated its regulatory opinion, Oxehealth Ltd had independently concluded that the Activity Tracker software did qualify as a medical device, self-declared the product as a Class I medical device and had registered the product with the MHRA.

111. However, following 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. The MHRA cannot comment on the reasoning behind Oxehealth's original self-classification conclusion.

112. The MHRA's position regarding the Activity Tracker reflects the principle that products are assessed by reference to their intended purpose rather than the technology through which they operate. Similar considerations apply to functions relating to activity monitoring, presence detection, location monitoring, and related alerts where those functions do not have a medical purpose.

113. In January 2024, the MHRA was informed by NHS England of an incident involving the death of a patient in a room fitted with the Oxevision platform. The information provided to the MHRA referred to the Activity Tracker function rather than the Oxevision Vital Signs medical device.

114. As the Activity Tracker was not considered to be a medical device, the matter fell outside the medical-device vigilance system and there was no requirement

for the manufacturer to report the incident to the MHRA under the Medical Devices Regulations 2002. NHS England was already aware of the incident and the MHRA took no further action.

Oxevision Sleep System

115. As set out in my first witness statement, the Oxevision Sleep System was not part of the MHRA's enquiries during the period described in this statement. Accordingly, the MHRA did not undertake any review or investigation of the Oxevision Sleep System.

116. The MHRA's enquiries focused on the Oxevision Vital Signs module and the regulatory status of the Oxevision Activity Tracker module. At that time, the Oxevision Sleep feature was not part of the matters under consideration and no concerns relating to the Oxevision Sleep System had been raised with the Agency.

117. The MHRA has disclosed all the substantive documentation relating to MHRA's involvement in the assessment and conclusions of the Oxevision Sleep System.

118. Subsequently, Oxehealth obtained regulatory certification for the Oxevision Sleep System. However, the MHRA has not undertaken any separate regulatory investigation concerning that product and no concerns relating to the Oxevision Sleep System were raised with the Agency during the period addressed by this statement.

Coordination with Other Bodies

119. I have been asked to provide clarification concerning the way in which the MHRA coordinates with other organisations where concerns arise that cross

regulatory boundaries, including where a technology incorporates both regulated medical-device functions and functions that fall outside the medical-device regulatory framework.

120. Where concerns arise that extend beyond the medical device regulatory framework, the MHRA may engage with or notify other organisations with relevant responsibilities, including NHS England, the Department of Health and Social Care, healthcare providers, the Care Quality Commission, the Information Commissioner's Office and other regulators.

121. Effective coordination and information sharing between organisations is essential for identifying and managing potential safety issues. The MHRA utilises active feedback from NHS England, as well as national reporting mechanisms, such as the National Reporting and Learning System (NRLS) used within NHS England. These facilitate the sharing and exchange of relevant information.

122. Information may be exchanged through both formal and informal arrangements between regulators, healthcare providers and other relevant organisations. Formal information-sharing arrangements assist in ensuring that safety concerns can be communicated effectively and establish agreed roles, responsibilities and mechanisms for collaboration.

123. The Medical Devices Market Surveillance and Vigilance framework supports the timely exchange of relevant safety information between organisations to enable appropriate assessment, investigation and regulatory action where necessary.

124. In relation to Oxevision, the MHRA's enquiries took place alongside enquiries being undertaken by NHS England and NHS Improvement. Information was exchanged and discussions took place regarding the respective responsibilities of the MHRA, NHS England, and healthcare providers in relation to the issues identified.

125. The MHRA considered matters relating to regulated medical-device functions, including the regulatory status of Oxevision Vital Signs, marketing claims that could imply a medical purpose, vigilance reporting obligations and the regulatory status of the Activity Tracker module. NHS England's interests extended more broadly to matters concerning deployment, implementation, operational patient-safety considerations and the use of the system within mental health inpatient environments.

126. Where a concern falls partly within and partly outside the MHRA's statutory remit, the MHRA considers those aspects that relate to regulated medical-device functions and, where appropriate, engages with organisations having responsibility for the remaining issues. In this case the MHRA engaged directly with NHS England regarding deployment and implementation concerns and with the Information Commissioner's Office regarding data-protection matters.

127. The MHRA's role remains focused on those aspects that constitute medical devices, whilst other organisations may have responsibility for non-medical-device aspects and the wider clinical environment in which the technology is deployed.

128. Accordingly, where risks arise from the interaction between regulated medical-device functions and non-medical-device functions, responsibility for identifying and mitigating those risks is not limited to a single organisation. Effective management of such risks requires contributions from manufacturers, healthcare providers, regulators and other relevant organisations, each acting within their respective responsibilities. MHRA maintains engagement with patients and the public through its Patient and Public Involvement and Engagement activities. Public-facing mechanisms include:

- i. Patient and Public Committees;
- ii. Workshops with patient groups;

- iii. Public webinars and consultation exercises;
- iv. Alongside direct engagement with key stakeholders.

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: 27/08/2026