Med Arcade Compliance and Safety Summary

BioSensum
July 2026
Prepared for: NHS procurement teams, information governance leads, and clinical governance review

About

This document provides a structured overview of BioSensum's regulatory status, data security framework, clinical safety approach, and NHS integration credentials. It is intended to support information governance review, NHS procurement evaluation, and clinical governance assessment.

For certificate copies, technical specifications, or formal procurement documentation, contact us directly at support@med-arcade.com.

Regulatory Status

MHRA Class I Medical Device

BioSensum is registered with the Medicines and Healthcare products Regulatory Agency (MHRA) as a Class I Medical Device under UK medical device regulations.
GMDN Code: 61087
UKCA conformity marking applied.

Intended Use

BioSensum is a clinical decision support platform intended to assist clinicians in reviewing and organising patient record information. It is designed to support clinical decision-making and does not replace clinical judgement. All clinical decisions remain the responsibility of the treating clinician.

Intended User

General Practitioners and specialist nurses working in NHS primary care settings during routine clinical activities including consultations, medication reviews, triage, and clinical assessments.

Use Environment

Cloud-based web or desktop application used on GP practice computers alongside existing Electronic Health Record (EHR) systems including Optum and TPP SystmOne.

Data Security and Privacy

ICO Registration

Med Arcade Ltd is registered with the Information Commissioner's Office (ICO) as a data controller under the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.
ICO Registration Number: ZB946240

UK GDPR Compliance

Med Arcade processes personal data in accordance with UK GDPR principles. Data is processed lawfully, transparently, and for specified purposes. Data subjects retain all rights afforded under UK GDPR including the right of access, rectification, and erasure.

NHS Data Security and Protection Toolkit (DSPT)
BioSensum meets the requirements of the NHS Data Security and Protection Toolkit, demonstrating compliance with the National Data Guardian's ten data security standards.

UK Data Residency
BioSensum's core clinical-processing infrastructure and data stores are hosted in the AWS London Region (eu-west-2). No patient data is transferred outside the United Kingdom.

Data Minimisation and Retention
BioSensum is designed to minimise clinical data processing. Time-limited caching is used with a current cache expiry of 24 hours. Data retention is managed by data type and purpose under the applicable approved retention schedule.

Audit events are encrypted at rest and minimise direct patient identifiers by using hashed identifiers where appropriate. Audit records retain the metadata necessary for traceability and investigation.

Access Controls
BioSensum uses multi-factor authentication, role and permission claims and security audit logging.

Cybersecurity

Cyber Essentials Certification
Med Arcade holds Cyber Essentials certification, demonstrating that fundamental cybersecurity controls are in place to protect against the most common cyber threats.

Penetration Testing
BioSensum has undergone independent penetration testing conducted by CHECK and CREST accredited security professionals. Testing covers application security, network security, and data handling procedures.

Security Controls Summary
- Encrypted data transmission over HTTPS/TLS
- Authentication, role/permission claims, and security audit logging
- Core services configured in the UK London Region
- AWS security monitoring through CloudTrail, GuardDuty, and Security Hub
- Documented incident-management and security-review processes

Clinical Safety

DCB0129 Clinical Safety
Med Arcade operates in accordance with DCB0129, the NHS clinical risk management standard for health IT systems. A qualified Clinical Safety Officer has been appointed and a clinical safety case has been established and maintained for BioSensum.

NHS Digital Technology Assessment Criteria (DTAC)
BioSensum has been assessed against NHS DTAC, the baseline criteria for digital health technology used in NHS settings. DTAC assessment covers clinical safety, data protection, technical security, interoperability, and usability.

Clinical Safety Approach
Before any clinical summary is generated, BioSensum's underlying system runs a deterministic

safety check layer that screens for allergy and medication conflicts, high-risk drug interactions, diagnosis conflicts, and timeline inconsistencies. This safety check is a fixed, non-negotiable step in the processing pipeline and cannot be bypassed.

Explainability and Traceability
Every insight surfaced by BioSensum links directly back to its original source document in the patient record. Clinicians can inspect the evidence basis for any output. This traceability is built into the system architecture, not added retrospectively, and creates an auditable record of what information informed each clinical review.

Limitations
BioSensum is not a diagnostic tool. It does not generate clinical diagnoses, prescribe treatments, or make autonomous clinical decisions. It surfaces and organises existing patient record information to support the clinician's own assessment. The clinician retains full clinical responsibility at all times.

NHS Integration

NHS IM1 Integration
BioSensum integrates with NHS GP systems through the NHS IM1 pathway, the standard compliance framework for third-party clinical software connecting to GP EHR systems including Optum and TPP SystmOne.

Current status: NHS IM1 Phase 1 approved.
Phase 2 integration requirements are currently being completed. Phase 2 approval will enable full integration and deployment across NHS GP practices.

EHR Compatibility
BioSensum is designed to work alongside, not replace, existing EHR systems. It connects to practice EHR systems via NHS-approved APIs, retrieves relevant patient data, processes it within BioSensum's secure environment, and surfaces structured outputs within the clinician's workflow.

Interoperability
Patient data is retrieved using coded clinical data via NHS-approved APIs. The platform is built to meet NHS Digital standards for clinical safety, data protection, interoperability, and technical assurance.

AI Safety and Governance

Proprietary Clinical Intelligence Architecture
BioSensum is not built on generic large language models. It is built around a purpose-built clinical intelligence system developed in-house and refined through real-world clinical feedback from working clinicians. This architecture is designed specifically for the safety, traceability, and workflow requirements of NHS primary care.

Hallucination Minimisation
A validation step checks every AI-generated citation against the underlying source data before display. Any citation that cannot be supported by the source record is removed before the output reaches the clinician. This step directly addresses the hallucination risk present in generic AI systems deployed in clinical settings.

Human Oversight

BioSensum outputs are intended for review by a qualified clinician before any clinical action is taken. The system is designed to support, not replace, human clinical reasoning. All outputs are clearly presented as decision support, not clinical instructions.

AI Regulatory Alignment

Med Arcade monitors developments in AI regulation including the EU AI Act and emerging NHS AI governance frameworks and is committed to maintaining alignment with regulatory requirements as they develop.

Cambridge Pre-Integration Pilot

Pilot Overview

Med Arcade conducted a pre-integration pilot of BioSensum at Arbury Road Surgery, Cambridge, in 2025. The pilot assessed whether BioSensum improves GP efficiency and decision-making when reviewing electronic health records.

Methodology

Four GPs participated using anonymised, consented patient records in a controlled environment. Eight patient records were used to simulate realistic primary care scenarios. Gold-standard clinical answers were predefined and reviewed by an independent GP observer. No real patients were involved in the pilot.

Results

- 50% reduction in time clinicians spent reviewing patient records.
- Fivefold reduction in mouse clicks required to surface clinically relevant information.
- All participating GPs reported improved confidence in the completeness of information reviewed before consultation.

Full pilot methodology and results are available in the Med Arcade White Paper (Version 2, July 2026).

Contact and Further Information

For formal procurement enquiries:
bernard@med-arcade.com

For certificate copies and technical documentation:
rapha@med-arcade.com

For clinical safety documentation (DCB0129 safety case, DTAC assessment):
support@med-arcade.com

Registered Office:
Med Arcade Ltd
London, United Kingdom
Registered in England and Wales
Company Number: 15751460
ICO Registration: ZB946240

This document is dated July 2026. Med Arcade Ltd reserves the right to update this document as regulatory status, certifications, and product capabilities develop. The most current version is available at medarcade.ai/resources.