G-Cloud 15 Service Definition Document

Service Type: Lot 2b - Software as a Service (SaaS)

Service Name: Zone Scribe

1. Service Overview

Zone Scribe is a UK-deployed Class I medical device providing cloud-based digital documentation and workflow support for UK health and social care organisations. It enhances documentation quality and efficiency through transcription, automated note generation, structured templates and multidisciplinary workspaces. All generated outputs require review and approval by the clinician. The service does not provide diagnostic, predictive, or treatment-related functions. Further information about the service is available at **https://www.zonescribe.com**

2. Regulatory and Clinical Safety Statement

Zone Scribe complies with MHRA requirements for Class I Medical Devices and is supported by a full Clinical Safety Case and Hazard Log developed in accordance with DCB0129, applicable to clinical systems deployed in the UK. These artefacts outline clinical risk controls, hazard mitigation and safety governance throughout the product lifecycle. As a UK-market service, Zone Scribe adheres exclusively to domestic regulatory, safety, and clinical governance frameworks.

3. Data Backup, Restore and Disaster Recover

Zone Scribe is hosted on AWS, benefiting from robust automated backup processes, multi–availability zone resilience, and industry-standard disaster recovery capabilities. Backups occur regularly, and data is replicated across protected environments to reduce the risk of loss. In the event of data corruption or system issues, point-in-time restoration is available where applicable. The service operates under a defined Disaster Recovery Plan that outlines recovery processes, target recovery times, and business continuity arrangements. Regular DR testing ensures the platform can be restored efficiently should a major incident occur, providing both operational continuity and assurance for customers.

4. Onboarding and Offboarding

Onboarding is supported through comprehensive online documentation, including HTML and PDF resources, along with guided in-platform tours and access to template libraries. Users can contact support via email for help with configuration, initial setup, or general guidance to ensure a smooth introduction to the service. When offboarding, customers retain full ownership of their data and can

export all content in standard formats such as MP3, WAV, PDF, HTML, or DOCX. The offboarding process incurs no additional charges, and once a customer confirms their data has been successfully extracted, Zone Scribe securely deletes any remaining data in accordance with its sanitisation policies.

5. Service Constraints

Zone Scribe occasionally requires planned maintenance, typically scheduled outside core business hours to minimise disruption. Customers are notified in advance of any such work. The platform supports a defined level of configuration through templates and workspaces; however, customisation is intentionally limited to maintain the integrity, security and performance of the service. As a cloud-based platform, Zone Scribe requires users to have a stable internet connection and a modern web browser. Certain features, such as real-time transcription, may require a microphone-enabled device.

6. Service Levels

The service is optimised for high performance and is designed to support fast transcription and document generation. Zone Scribe operates with a target availability consistent with industry-standard cloud services, and customers receive email-based support during UK business hours. Issues are triaged based on severity to ensure critical matters are handled promptly and effectively. Regular monitoring and performance management ensure that the service remains responsive and reliable under varying demand levels.

7. After-Sales Support

After implementation, customers receive continued access to support via email for troubleshooting, configuration queries, platform navigation and usage guidance. The team also provides ongoing access to updated documentation, release notes, and feature explanations to help organisations maximise the value of the service. Zone Scribe does not offer tiered support services; all customers receive the same level of assistance without additional charges.

8. Technical Requirements

The service is accessed through a modern web browser and requires a stable internet connection. Users must have valid login credentials issued by their organisation. Devices with microphone capability may be needed for transcription functions. No specialist hardware or software installations are required, enabling easy deployment across a wide range of devices.

9. Outage and Maintenance Management

If an outage occurs, the support team notifies users by email once the issue has been confirmed, explaining the nature of the problem and the start of the investigation. During the incident, further email updates are provided to share progress, available workarounds and any estimated timelines for resolution. When service is restored, a final email confirms resolution and outlines any impact and

key actions taken. Where appropriate, an optional post-incident summary can be provided, offering insight into root causes and preventative steps taken to reduce future risk. Planned maintenance is similarly communicated in advance to minimise operational impact.

10. Hosting Options and Locations

Zone Scribe is hosted exclusively within UK AWS regions. Data does not leave the UK at any stage, ensuring complete alignment with UK GDPR, NHS data residency requirements and wider national data protection regulations. AWS provides a secure, resilient infrastructure with comprehensive physical and environmental controls.

11. Access to Data on Exit

Customers retain full ownership and control of their data throughout their use of Zone Scribe and during offboarding. Upon exit, all data can be exported in widely supported formats suitable for long-term storage or migration to another system. After data extraction is confirmed by the customer, Zone Scribe securely deletes the data in full compliance with UK GDPR and NHS guidance on secure data destruction.

12. Security

Security is fundamental to the service's architecture and operational governance. All data is protected through robust encryption mechanisms, with encryption applied both in transit using industry-standard TLS protocols and at rest using secure, managed encryption services. Access to the platform is controlled through strict role-based access controls (RBAC), ensuring users can only access the functions and information appropriate to their role. Comprehensive audit trails capture key administrative and user activities, supporting forensic analysis, compliance monitoring and full accountability across the system. Secure development practices are embedded throughout the product lifecycle, including code review, vulnerability scanning, dependency management and controlled release pipelines, ensuring that security considerations are addressed from design through to deployment.

The service complies fully with UK GDPR and the Data Protection Act 2018, with appropriate organisational and technical measures in place to safeguard personal and special-category health data. The organisation is certified to ISO 27001, demonstrating a mature and audited information security management system, ISO 9001, evidencing strong quality management and continual improvement processes, ISO 42001, demonstrating a governed Artificial Intelligence Management System, and ISO 14001, evidencing a certified Environmental Management System. The platform also meets Cyber Essentials Plus, confirming independent verification of technical controls against common cyber threats, and achieves Standards Exceeded within the NHS Data Security and Protection Toolkit (DSPT). Zone Scribe is also ORCHA Assured (Bronze, UK | EU), providing independent assurance of the product's clinical safety, data privacy, usability and accessibility. Together, these accreditations provide a high-assurance security and governance framework appropriate for UK healthcare environments, ensuring confidentiality, integrity and availability of all data processed through the service

13. Summary

Zone Scribe is a cloud-based digital documentation and workflow support product designed for UK healthcare environments and registered as a Class I Medical Device in full compliance with MHRA requirements. Its operation is supported by a comprehensive Clinical Safety Case and Hazard Log developed under DCB0129, ensuring clinically safe deployment and use.

The product improves the efficiency and accuracy of clinical documentation through transcription, automated note generation, structured templates and collaborative workspaces, with all outputs requiring clinician review before inclusion in patient records.

Hosted in AWS UK/EU regions, Zone Scribe benefits from secure, resilient infrastructure, including regular backups, multi-zone redundancy and a robust Disaster Recovery Plan. The service is delivered within a strong assurance framework, holding ISO 27001, ISO 9001, ISO 42001, ISO 14001, Cyber Essentials Plus, DSPT Standards Exceeded, and ORCHA Assured (Bronze) status.

Onboarding provides access to online documentation and email support, while offboarding includes full data export at no additional cost, followed by GDPR-aligned secure sanitisation. Customers maintain full ownership of their data, which is encrypted, access-controlled and fully auditable, ensuring compliance with UK GDPR and broader healthcare data protection standards.

Full details of our security posture are available on: **www.zonescribe.ai/trust/**

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