

To Whom It May Concern

Re: Surgery Intellect's Compliance with NHS England AVT Requirements

Surgery Intellect powered by TORTUS - provides complete Compliance with NHS England AVT Requirements

Executive Summary: Surgery Intellect complies with all NHS England requirements for Ambient Voice Technology laid out in the Priority Notification dated 9th June 2025 from Dr Alec Price-Forbes, National Chief Clinical Information Officer. Surgery Intellect exceeds standards in multiple areas, and we maintain comprehensive governance oversight across all deployments over and above the standards prescribed.

V2.0 Executive Summary Update: X-on Health confirms that Surgery Intellect has been assessed against the latest NHS England guidance for AI-enabled ambient scribing products (Version 3) and continues to align with the applicable requirements relating to clinical safety, information governance, data protection, AI governance, cybersecurity and supplier assurance. This document version (V2.0) provides an updated position on compliance, including enhancements implemented since the original publication (V1.0) of this assessment.

This letter serves as formal confirmation that *Surgery Intellect*, a product of **X-on Health Ltd**, powered by **TORTUS**, fully complies with all NHS standards for Ambient Voice Technology (AVT) solutions. X-on Health, as the contracting entity, ensures full alignment with NHS requirements, underpinned by a strong commitment to clinical safety, data protection, and operational excellence. With robust DPIAs already in place, including a comprehensive overarching DPIA, Surgery Intellect is now being introduced to the market, delivering

advanced, voice-enabled clinical support seamlessly into surgical workflows across all care settings. X-on Health recognises that final deployment assurance remains the responsibility of the purchasing NHS organisation. To support this, X-on Health provides supporting documentation including DTAC evidence, DSPT submissions, clinical safety documentation, DPIA support materials and implementation guidance.

X-on Health has exclusive rights to offer the TORTUS AVT solution to primary care in the UK and will be the contracting party with Tortus AI, a named sub-contractor. The TORTUS AVT solution has been approved for deployment in various NHS settings including primary care, secondary care, A&Es, mental health trusts, and ambulance services.

Core Platform Assurance Requirements

Requirement	Tortus AI Compliance	X-on Health Compliance	Compliant
NHS England AVT Supplier Registry Link	Registered supplier with supporting assurance evidence available through the NHS England AVT Supplier Registry.	Registered supplier (for Surgery Intellect) with supporting assurance evidence available through the NHS England AVT Supplier Registry.	✓
DTAC Ready	Full DTAC (NHS v2.0) compliance achieved across all five pillars. ISO 27001 certified Tortus DTAC	DTAC Ready (NHS v2.0) with all five pillars met. ISO 27001 certified Surgery Intellect DTAC Document	✓
DSPT	'Standards Exceeded' status (ODS: O2G5U) DSPT Report	'Standards Exceeded' status (ODS: 8JM42) DSPT Report	✓

Cyber Essentials	Achieved. Cyber Essentials Certification	Achieved. Cyber Essentials Cyber Essentials Plus	✓
CREST-approved Pen Testing	Regular CREST-approved testing Application Retesting Report	Regular CREST-approved testing Penetration Testing Report	✓
DCB0129 Compliance and Named Clinical Safety Officer	Fully compliant with DCB0129 clinical risk management standard. Dr. Youssef Oskrochi (Curistica) (Named CSO)	Fully compliant with DCB0129 clinical risk management standard. Dr. Imran Khan (Named CSO)	✓
Encryption	AES-256 at rest, TLS 1.2+ in transit, MFA, SSO, RBAC; ISO 27001 certified	AES-256 at rest, TLS 1.2+ in transit, MFA, SSO, RBAC; ISO 27001 certified	✓
GDPR Compliance	Full GDPR compliance with UK/EU data sovereignty	Full GDPR compliance with UK/EU data sovereignty	✓
No Unsafe Functionality	Aligned with DCB0129 and ISO 14971 standards. ISO 13485 (QMS for medical devices) certified. Tortus's proprietary clinical safety system " The Shell " removes 92.7% of hallucinations. ISO 13485:2016 Certificate	Aligned with DCB0129 and ISO 14971 standards. All outputs generated by Surgery Intellect are draft outputs. The responsible healthcare professional is responsible for reviewing, amending where necessary, and approving content before saving to the clinical record.	✓
NHS System Integration	Native integration with Epic, Medicus and more; Oracle available site-by-site; EMIS/TPP integration	Direct API integration with EMIS and SystmOne/TPP, including write-back to patient record; FHIR R4 &	✓

	supported via X-on Health; FHIR R4 & HL7 v2 compliant with write-back.	HL7 v2 compliant; integration underpins Tortus support.	
Translation Accuracy Responsibility	No language translation; full transcription responsibility	No language translation; full transcription responsibility	✓

In addition to the above, X-on Health maintain the following ISO certifications:

- Quality Management System: [ISO 9001:2015](#)
- Environmental Management System: [ISO 14001:2015](#)
- Business Continuity Management System: [ISO 22301:2019](#)
- AI Management System: [ISO 42001:2023](#)

For further information, including full governance documentation and customer templates, please visit the [X-on Health Trust Centre](#) and [Tortus AI Trust Centre](#) respectively.

Enhanced Requirements

Requirement	Tortus AI Compliance	X-on Health Compliance	Compliant
Medical Device Classification	MHRA Class IIa medical device under UK MDR 2002 MHRA Registration Certificate	Supports Tortus AI's medical device registration	✓
Data Protection	Automatic deletion of patient session data after 24 hour Trust Centre	Secure retention in-line with NHS Record Management (2023) and NHS contractual requirements for Advanced Cloud Telephony. Trust Centre	✓
System Integration	Native integration with Epic; Cerner available site-by-site; EMIS/TPP integration supported via X-on; FHIR R4 & HL7 v2 compliant with write-back.	Direct API integration with EMIS and SystmOne/TPP, including write-back; FHIR R4 & HL7 v2 compliant; integration underpins Tortus support.	✓

AI Governance & Oversight	Tortus's proprietary clinical safety system " The Shell " for hallucination reduction.	AI Management System certified to ISO 42001 .
	Ongoing monitoring of model performance, in-line with ISO 13485.	Defined incident management, monitoring and escalation mechanisms.
	Defined incident management, monitoring and escalation mechanisms.	Explicit human review required before any content is filed back to the patient record.

Clinical & Operational Threshold Benefits

Requirement	Compliance	Compliant
Evidence of NHS Clinical Validation	Tortus AI AVT is validated via NHS clinical studies: 17,000-patient study. Data from our Phase IV study with 473 patient observations shows a 16.9% increase in direct patient care time - Tortus real-world evaluation spanning 4,890 consultations has achieved a 99% acceptance rate. Clinical satisfaction metrics show that 97% of clinicians report the ability to give full attention to patients, compared to just 67% at baseline, and 82% of clinicians rate their experience as better than previous clinics without AVT. - Tortus London Ambulance Service Trial. AVT shortened assessments by two minutes and increased throughput by 15%.	✓
Economic Justification and Workforce Impact	- Tortus AI's economic modelling shows a return on investment of 30-40x through multiple value streams. GOSH-led Tortus trial: 23.5% more direct patient interaction time and a 35% drop in clinicians feeling overwhelmed by note-taking. Golborne Canalside Surgery: Surgery Intellect customer reporting 22 hours of admin time saved in the first 4 months of use.	✓

Patient Transparency and Practice Support

X-on Health supports GP Practices in deploying Surgery Intellect and in meeting patient transparency requirements by providing:

- Patient information materials
 - Posters
 - Newsletters/website information
 - Digital display templates
 - Email/SMS templates
- Deployment guidance
 - Help Guides for all Surgery Intellect functionality and best practice.
 - CPD-accredited X-on Health Academy course learning platform
 - Access to Product Trainers and Support Teams
- Implementation support
 - Template DCB0160 Hazard Log
 - Template DPIA document
- Recommended communication approaches for informing patients when ambient scribing technology is being used

Commitment to Ongoing Compliance

Surgery Intellect maintains continuous compliance through regular engagement with ICBs, quarterly clinical safety reviews, and proactive regulatory submissions. As the contracting entity, X-on Health ensures that our governance framework not only meets but exceeds NHS requirements, setting the benchmark for Ambient Voice Technology (AVT) deployment in clinical environments.

Tortus AI recently demonstrated commitment to ongoing compliance by achieving MHRA Class IIa medical device status on 24th June 2026.

We welcome further scrutiny and remain fully available for audit or clarification regarding our compliance framework. Our team is committed to supporting NHS England's vision for safe, effective AVT adoption across all care settings.

Please refer to the following sections for supporting documentation and additional details. If you require further information or would like to discuss any aspect of our compliance framework, do not hesitate to contact our Governance team, (governance@x-on.co.uk).

Yours sincerely,

Derrick Measham
Innovation Director
X-on Health
Email: derrick.measham@x-on.co.uk

Confirmed as an accurate reporting of Tortus AI AVT solution by:

Dr Dominic Pimenta
MBBS MRCP BSc (Hons)
Chief Executive Officer
Tortus AI
Email: commercial@Tortus.ai

Appendix A - Changes Since Initial Publication (V1.0 to V2.0)

- Updated Product Logo on Header
- Added clarification on new NHS guidance on the use of AVT
- Updated Core Platform Assurance Requirements for latest versions
 - Updated DTAC, DCB0129, CE & CE+ links, Tortus CSO, ISO 13485 certification, ISO certificate links, file to record approved for X-on Health for EMIS Web and TPP SystemOne.
- Enhanced Requirements
 - Tortus Class IIa medical device updates. Data Protection stance detailed further.
 - Added AI Governance and Oversight section.
- Clinical & Operational Threshold Benefits
 - Updated for new evidence and case studies to further support Clinical and Operational benefits claimed.
- Added Patient Transparency and Practice Support section