TORTUS

PRESS RELEASE

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TORTUS becomes the first AVT to achieve UKCA Class IIa certification.

The certification places clinical AI in the same regulatory category as the medical equipment used directly in patient care. A UK Approved Body has reviewed the evidence behind TORTUS, and judged it safe enough to help write the record.

LONDON, 1 July 2026. TORTUS today became the first ambient voice technology to achieve UKCA Class IIa certification, the UK medical device standard overseen by an Approved Body. The technology listens during a consultation and drafts the summary, notes, referral letters and clinical coding a clinician would otherwise write by hand, and it has already supported the care of more than 2.5 million patients across the NHS. Nothing it produces enters a patient's record until a clinician has read and approved it.

Certification at this level is not a self-declared badge. It means an independent Approved Body, one of only a handful in the world permitted to assess medical software, has examined TORTUS against the highest level of assurance available and reviewed a clinical, technical and safety evidence base running to thousands of pages. The certificate is explicit about the limits: TORTUS assists clinicians in the diagnostic pathway, but does not diagnose, recommend treatment or replace clinical judgement.

TORTUS is not alone in pursuing this standard, and that is a good thing for the field. A small number of ambient voice tools have sought certification under the European regime, which raises the floor for everyone and is welcome. TORTUS is the first to clear the bar set by the UK's own regulator, under the certification the NHS will increasingly be able to ask for by name.

The evidence behind the certification has been published. In a multi-site study led by Great Ormond Street Hospital, covering more than 16,000 patient encounters across nine NHS sites, clinicians using TORTUS spent 23.5% more time in direct patient care. In a dedicated emergency department study, clinicians saw 13.4% more patients per shift and reached their first written record 51.7% faster.

For NHS leaders and procurement teams, the company argues the certification simplifies a genuinely hard buying decision. "In past procurements, we have seen buyers struggle to define what good looks like, which is fair: AI is still new, and buying it well is nearly as hard as building it," said Dr Pimenta, recently named one of the HSJ's 50 most influential NHS healthtech leaders. "Class IIa creates a category that arrives pre-vetted, where independent due diligence has already been done to a depth no single bid evaluation could reach. It turns a difficult judgement into a clear standard a buyer can require."

TORTUS works inside the systems clinicians already use rather than adding another screen alongside them. It runs within established electronic patient record platforms including Epic and Cerner, and reaches the point of care through partnerships such as X-on and, most recently, Limbic. Trusts do not have to replace what they already run to adopt it. The certification covers use in England, Scotland and Wales, across primary, secondary, pre-hospital and emergency care, with safety monitoring deepening as deployment grows.

"Scaling clinical technology means moving a complex technological, regulatory and commercial agenda at once," said Jean-Marie Ferdègue, Chief Technology Officer, previously at Babylon Health, Trainline and Meta. "Our priority is making safety scale as fast as demand: technology that is certified, evidenced and ready for the most complex clinical settings."

> In healthcare, regulation is the gate to deployment and trust, not the barrier.
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> DR DOMINIC PIMENTA · CEO AND CO-FOUNDER, TORTUS

"While some vendors see regulation as standing in the way of progress, clinicians know the truth. In healthcare, regulation is the gate to deployment and trust, not the barrier," said Dr Pimenta. "And this matters beyond the world of today, where AI drafts the notes, to the world of tomorrow, where the same interface takes actions and summarises records autonomously. Class IIa moves AVT from a goal in itself to the foundation that unlocks what comes next. In the same way we led on AVT in the NHS, we are already exploring those frontier use cases with partner trusts."

About TORTUS

TORTUS is the UK's first ambient voice technology company, founded by NHS doctors, building clinical technology that earns its place at the bedside. Its flagship product, TORTUS, is the first ambient voice technology to achieve UKCA Class IIa certification. It supports clinicians during patient consultations by listening to live or recorded audio and drafting consultation summaries, medical notes, referral letters and clinical coding, all of which a clinician reviews and approves. TORTUS is in use across primary,

secondary, pre-hospital and emergency care, and has supported the care of more than 2.5 million patients across the NHS. It is certified for use in England, Scotland and Wales.

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NOTES TO EDITORS

The certified facts, please report accurately

WHAT CLASS IIA MEANS	Class IIa is a medical-device safety category. Certification at this level means an independent Approved Body, not the manufacturer, has assessed the product against the highest level of assurance and reviewed its full clinical and technical evidence base. Only a handful of bodies worldwide are permitted to carry out this assessment for medical software.
DEVICE & MANUFACTURER	TORTUS, by TORTUS AI Ltd, 5 Brayford Square, London E1 0SG.
INTENDED PURPOSE (PER CERTIFICATE)	TORTUS is a clinical decision support tool intended to be used by healthcare professionals in primary, secondary, pre-hospital and emergency care settings to assist them in the diagnostic pathway during patient consultations, by transcribing live or recorded audio and generating automatic outputs including consultation summaries, medical notes, referral letters and standardised clinical coding. TORTUS does not independently diagnose or recommend treatment and is not intended to replace clinical judgement. All outputs require review and approval by the responsible healthcare professional before integration into the patient's medical record.
CLASSIFICATION	Class IIa standalone medical device software. Device Category MD 1111 (Software), under Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 (as modified by Part 2 of Schedule 2A).
CERTIFIED BY	Scarlet NB UK Ltd, UK Approved Body 8536, 12 New Fetter Lane, Holborn, London EC4A 1JP. Signed by James Dewar, Director, under a Full Quality Assurance System.
CERTIFICATE	Certificate number SCAR-16.5.1.0, issued 24 June 2026, expiry 23 June 2031. Audit report reference UKQREP-16.5.1.0. Subject to periodic surveillance and MHRA registration.
TERRITORY	The certificate covers use within Great Britain. TORTUS is being deployed in England, Scotland and Wales. It is not in use in Northern Ireland, which operates under separate rules.
FIRST OF ITS KIND (UKCA VS CE)	TORTUS is the first ambient voice technology to achieve UKCA Class IIa certification, the UK's own medical device regime, assessed by a UK Approved Body. This is a distinct certification from a CE mark. Some ambient voice products hold EU MDR Class IIa

	certification under the separate European regime, assessed by an EU notified body. CE-marked devices currently retain transitional recognition in the UK market, but that recognition is not the same as holding a UKCA certification. TORTUS is the first AVT to hold the UK mark itself.
REGULATORY WORDING	TORTUS is a UKCA Class IIa certified medical device. The Approved Body (Scarlet) certifies the device; MHRA registration is a separate step and is in progress. Please do not report this as "MHRA-certified."
SCOPE OF USE	Web-based software on internet-connected desktop, laptop or tablet, for English-language consultations. Not intended for use on mobile phones or offline. For use by registered healthcare professionals only.
EVIDENCE SOURCES	Direct-care finding (23.5%): "Time to Care," Wray, Mahdi et al, GOSH-led multi-site study, Lancet preprint (SSRN 5350619), 165 clinicians and 16,470 encounters across 9 sites. Emergency findings (13.4% more patients per shift, 51.7% faster first documentation, both statistically significant): "Unlocking Clinical Time in Emergency Departments," Mahdi et al, Lancet preprint (SSRN 5350615), tertiary London ED. Both are non-peer-reviewed preprints; describe as such.
FOCUS	This release is limited to the certification. Any funding announcement will be made separately so it does not dilute the safety message.

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