FINAL PMS CONCLUSION

Tom Thumb Infant Resuscitator - Legacy MDD Device

Class IIb - legacy MDD device	**Reviewer:** Derek Lamb	**Review:** 10 Aug 2026
Final finished-device supply: 24 Mar 2020	**Invoice:** RVM121752-1	**Units:** 6 x TT480

Product status and PMS scope

The Tom Thumb range was progressively withdrawn from active manufacture and sale as Viamed elected not to transition the product to MDR. The final identified finished-device supply is evidenced by invoice **RVM121752-1 dated 24 March 2020**, recording **six TT480 units (0310030), S/N 0401624-0401629**. No evidence has been identified of routine commercial supply of newly manufactured Tom Thumb finished devices after this date. Later transactions represent servicing, repair, spare parts, accessories and legacy support.

Viamed will continue proportionate PMS and risk re-evaluation **for as long as servicing/support of the installed Tom Thumb population continues**. Service and repair activity provides continuing real-world information on the condition and performance of this mature installed base.

Serviceability and risk-management conclusion

Continued servicing does not automatically extend the acceptable service life of an individual device. Each returned device is subject to applicable servicing, inspection, functional testing, calibration and QA and is returned for continued use only where it meets the established service specification. Devices that cannot be restored to specification should not be returned to service.

The 2026 review found activity to be predominantly routine servicing and replacement/adjustment of expected serviceable components. One new repair code - **"Replaced adjustable valve spring"** - occurred once in 1,692 records (0.06%) and was separately assessed as routine calibration/service activity, with negligible/improbable residual risk and no CAPA required. No systematic product deterioration or new hazardous failure mechanism was identified.

Clinical, vigilance and regulatory clarification

Current Resuscitation Council UK 2025 guidance continues to recognise T-piece resuscitation, including T-piece devices capable of CPAP or positive-pressure ventilation with PEEP. This supports the continued clinical validity of the underlying T-piece principle; it does not imply that the discontinued Tom Thumb is a newly marketed product. A supplementary FDA MAUDE review did not identify a Tom Thumb-specific safety signal.

MHRA guidance states that the strengthened GB PMS requirements introduced from 16 June 2025 do not apply where no further individual devices of a discontinued model are placed on the GB market or put into service after that date; such discontinued devices remain subject to the prior PMS requirements. The final identified Tom Thumb finished-device supply predates this date by more than five years.

Complaints / vigilance / field safety actions

No new Tom Thumb customer complaint presenting a new safety concern, reportable serious incident, Field Safety Corrective Action, recall or new regulatory notification requirement was identified during this review. Any future serious incident, significant adverse trend, recurring safety-related fault or previously unidentified hazardous situation will be escalated through Viamed complaint, vigilance, CAPA and risk-management processes.

OVERALL CONCLUSION

The 2026 Tom Thumb Post-Market Surveillance and Risk Assessment Re-evaluation has identified **no new or unacceptable risk** associated with the existing installed population. The available evidence does not indicate a systematic product failure, deterioration in the established benefit/risk position or a previously unidentified hazardous situation. Existing risk-management controls remain appropriate and no CAPA, FSCA, recall, change to historic intended purpose or regulatory notification is indicated.

The benefit/risk determination for continued use of serviceable legacy Tom Thumb devices remains acceptable, provided individual devices continue to meet the established Viamed servicing and QA specification.

Viamed will continue proportionate PMS for as long as it continues to service/support the installed population. The PMS programme may be formally closed when servicing/support ceases, subject to continuing statutory record-retention, vigilance and regulatory obligations.

Evidence / external sources reviewed

Viamed: Invoice RVM121752-1 (24 Mar 2020); Tom Thumb PMS Risk Assessment Re-evaluation (10 Aug 2026).

Resuscitation Council UK: 2025 Newborn Resuscitation Guidelines - www.resus.org.uk/professional-library/2025-resuscitation-guidelines/newborn-resuscitation-and-support-transition-infants-birth (reviewed 10 Aug 2026).

MHRA / GOV.UK: Medical devices: PMS requirements - Introduction and scope, discontinued devices - www.gov.uk/government/publications/medical-devices-post-market-surveillance-requirements/introduction-and-scope (reviewed 10 Aug 2026).

US FDA: Manufacturer and User Facility Device Experience (MAUDE) Database - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/textsearch.cfm (reviewed 10 Aug 2026).

Review completed: 10 August 2026	**Reviewed by:** Derek Lamb