In accordance with
2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007
Annex X 1.1b

Demonstration of conformity with essential requirement based on clinical data is not appropriate as the product was originally designed and manufactured in the 1990's before the introduction of the CE mark and associated procedures.

Viamed has been unable to locate any references to formal clinical investigation as specified under Annex X. for T-piece occluders.

Mercury Medical USA " Guidelines for resuscitation" " WORKSHEET for Evidence-Based Review of Science for Emergency Cardiac Care Worksheet " also searched. This report from Mercury lists the references to the keywords from 2004 to 2009.

All references appear to be revolve around the discussion between the techniques of T-occluders and hand bag mask ventilation. This has resulted in declarations that both perform the same task and each has advantages.
All references prior to 2004 are small scale trials not in accordance with Annex X but are valuable that they form the basis of the current NHS Guidelines on Neonatal resuscitation.
"Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review" From the Official Journal of the European Resuscitation Council
confirms the Tom thumb is a T-Piece resuscitator. Other papers from 1983 (Viamed information) involving clinical data confirm that the Tom Thumb, by name, is demonstrated as an equivalent to the Fisher & Paykel Neo Puff and other commercially available T-piece occluder ventilators.
This can be proved in the basic design files that the devices apply basic rules of physics, are similar and perform exactly the same clinical function. They are therefore interchangeable in references to papers.
None of the researched papers criticise the use of T-occluders and by inference Tom Thumbs.

Clinic efficacy has been demonstrated by the numbers of these devices in use and there regular application
There are approximately 250 Neonatal units in the UK. Approximately 10 intensive cots/incubators/or intensive care systems with overhead heaters. I.e 2.500 workstations.
If used 24/7 is a potential of 900,000 per year. If only 10% are used that is still 90,000 p.a.
The units have been in use since 1993 on an increasing scale. There is no notification of any Tom Thumb not performing according to specification.

There are residual risks. The unit should be serviced (in accordance with the service manual page 3 introduction) every two years (a legal statement based on the manufacturers life of the elastomer's used. In practice units have been returned for service in good working order after 15 years of continuous use. Service training is available to hospital/OEM technicians.
The units are heavy and can be damaged if dropped. This has rarely happened and has resulted in damaged pressure gauges.
The greatest risk to patient safety has been the omission of the Tom Thumb from the ventilating circuit by clinical staff braking the hospital protocols.
Miss connection of tubing has usually been avoided by the use of different size fittings. However hospitals regularly use flow meter to mask circuits on a routine basis.
There is a risk that the protocols could be written too loosely and allow pressures from the flow meter to reach the patient. This has been limited by using a fixed blow off valve restricted to 45mmHg

The Tom thumb is manufactured from brass (no plastic parts) so is robust and has a long life.
It is manufactured assembled and by Viamed in the UK working under ISO 13485 .
Every device is checked & calibrated with standard gauges prior to despatch.
It conforms to the Essential Requirements which are continually being updated in line with the current Meddev.
Since its inception there have been no Hazard warnings, or product recalls.

John S Lamb
31 August 2016