Format for Clinical evaluation

1.	**General Details**	
1.1	State the proprietary name of the device	Tom Thumb resuscitator
1.2	Any code names assigned during device development.	
1.3	Identify the manufacturer(s) of the device.	Viamed
2.	**Description of the device and its intended application**	**Location of Document**
2.1	Provide a concise physical description of the device	F1 Description of Device Technical Files Doc 7458 Y1 Theory of device
2.2	Cross referencing to relevant sections of the manufacturer's technical information as appropriate	
2.3	The description should cover information such as:	
2.4	materials	T 1 Specifications of Materials : T 2 Material Safety Data Sheet
2.5	whether it incorporates a medicinal substance	N/A
2.6	(already on the market or new	Y 1 IMI positive pressure ventilator L 1 Neopuff RD900 E 5.3 Competitor instructions for use
2.7	tissues	N/A
2.8	blood products;	N/A
2.9	The device components, including software and accessories;	Doc 2267, 2266 Photographs of sub assemblies R 1 Component breakdown T 1 Specifications of materials NeoPeep Doc 8512
2.10	mechanical characteristics;	
2.11	others, such as sterile vs. non-sterile,	non-sterile,
2.12	radioactivity etc.	N/A
2.13	State the intended application of the device	Neonatal resuscitation
2.14	Single use	Only mask and tube non Viamed NeoPeep Doc 8512
2.15	Re-useable	Yes
2.16	invasive/non invasive	non invasive
2.17	implantable;duration of use or contact with the body; organs, tissues or body fluids contacted by the device.	N/A
2.18	Describe how the device achieves its intended purpose.	F1 Description of device Doc. 7458 Y1 Theory of device
3	**3. Intended therapeutic and/or diagnostic indications and claims**	Resuscitation
3.1	State the medical conditions to be treated. including target treatment group and diseases.	Breathing difficulties
3.2	Outline any specific safety or performance claims made for the device	L 1 Promotional material Doc 14433
4	**4. Context of the evaluation and choice of clinical data types**	
4.1	Outline the developmental context for the device. The information should include whether the device is based on a new technology, . The amount of information will differ according to the history of the technology. Where a completely new technology has been developed, this section would need to give an overview of the developmental process and the points in the development cycle at which clinical data have been generated. For long standing technology, a shorter description of the history of the technology (with appropriate references) could be used. Clearly state if the clinical data used in the evaluation are for an equivalent device.	Uses the basic physics principle of the Tee occluder. I.e gas will choose the line of least resistance. Has been used as the basis for Neonatal ventilation since the early 1970's Bourns, Drager, Sechrist. SLE etc. Simple Tee occluders include IMI , F&P Neopuff, Clinical data is for all devices. The variations are in the electronic control of inspiration/expiration

		times (controlled manually in the Tom Thumb.
4.2	a new clinical application of an existing technology,	
4.3	or the result of incremental change of an existing technology	
4.4	Identify the equivalent device(s) and provide a justification of the equivalency, cross-referenced to the relevant non-clinical documentation that supports the claim.	Y 1 IMI positive pressure ventilatorL 1 Neopuff RD900 E5.3
4.5	State the Essential Requirements relevant to the device in question, in particular, any special	C 1 Essential requirements Doc 13659 , doc 9441 & doc 2172
4.6	design features that pose special performance or safety concerns (e.g. presence of medicinal,human or animal components) that were identified in the device risk management documentation and that required assessment from a clinical perspective.	N/A
4.7	Outline how these considerations were used to choose the types of clinical data used for the evaluation. Where published scientific literature has been used, provide a brief outline of the searching/retrieval process, cross-referenced to the literature search protocol and reports.	N/A
5	**5. Summary of the clinical data and appraisal**	
5.1	Provide a tabulation of the clinical data used in the evaluation, categorised according to whether the data address the performance or the safety of the device in question. (Note: many individual data sets will address both safety and performance.) Within each category, order the data according to the importance of their contribution to establishing the safety and performance of the device and in relation to any specific claims about performance or safety.	Doc 9358 data without clinical trial
5.2	Additionally, provide a brief outline of the data appraisal methods used in the evaluation, including any weighting criteria, and a summary of the key results.	Google
5.3	Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.	Doc 15411 RVI Newcastle . Doc 1165 Bradford Royal Infirmary.
5.4	Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.	E 5.3 Competition instructions L 1 Literature reviews Clinical papers Doc 15497 L 1
	6. Data analysis	
6.1	**Performance**	
6.1.1	**Provide a description of the analysis used to assess performance.**	
6.1.2	Identify the datasets that are considered to be the most important in contributing to the demonstration of the overall performance of the device and, where useful, particular performance characteristics.	
6.1.3	Outline why they are considered to be "pivotal" and how they demonstrate the performance of the device collectively (e.g. consistency of results, statistical significance, clinically significance of effects).	
6.2	**Safety**	
6.2.1	Describe the total experience with the device, including numbers and characteristics of patients exposed to the device; and duration of follow-up of device recipients.	Many thousands since 1993. Serious incidents have all related to misuse (Tom Thumb) bypassed by users. Mainly Physicians
6.2.2	Provide a summary of device-related adverse events, paying particular attention to serious adverse events.	H 2 User Feedback H 3 Analysis of complaints
6.2.3	Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.	Part of the Neonatal resuscitation Hospital protocols and guidelines
6.3	**Product Literature and Instructions for Use**	
	State whether the manufacturer's proposed product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.	L 1 Promotional literature Neopuff RD900 F 5 Instructions for use Doc 2185 Tom Thumb original leaflet
	7. Conclusions	
7.1	Outline clearly the conclusions reached about the safety	The device has been on the market since 1993. It was designed under the guidance of Professor Lister Princess Mary Hospital Newcastle who's prototypes manufactured by

		Medical Physics had been successfully used to resuscitate neonates for several years. The Tom Thumb has been used continuously and successfully without major failure
7.2	and performance of the device from the evaluation, with respect to the intended use of the device.	
7.3	State whether the risks identified in the risk management documentation have been addressed by the clinical data.	
7.4	For each proposed clinical indication state whether:	
7.5	the clinical evidence demonstrates conformity with relevant Essential Requirements;	C 1 Essential requirements Doc 9441 ,2172 & 13659
7.6	the performance and safety of the device as claimed have been established; and	Yes safety record
7.7	the risks associated with the use of the device are acceptable when weighed against the benefits to the patient	E 3 Risk Analysis report Doc 2182 ,15429 E 4 EN ISO 14971 Annexe A E 5 EN ISO 14971 Annexe D