CLINICAL EVALUATION REPORT

Product

	Action	Doc. Location	Status
1	State the proprietary name of the device	CE File	
	Code names assigned development.	Y1: Y2: Y11	
	Identify the manufacturer(s) of the device.	J3	
2	Provide a concise physical description of the device Cross referencing to relevant the manufacturer's technical information as appropriate	F1	
	The description should cover information such as:materials	R1: T1	
	Whether it incorporates a medicinal substance	Z8	
	Human tissues,	Z12	
	Blood products;	Z13	
	Device components	R1: T1	
	Software	Y19	
	Accessories;	F4	
	Mechanical characteristics		
	Sterile	O1	
	Non sterile	O1	
	Radioactivity	Z12	
	Single use/reusable; invasive/non implantable	G4	
	Duration of use or contact with the body; organs, tissues or body fluids by the device.	D1;D6	
	State the intended application of the device -;	F5	

	Describe how the device achieves its intended purpose.		
3	Intended therapeutic and/or diagnostic indications and claims		
	State the medical conditions to be treated, including target treatment group and Outline any specific safety or performance claims made for the device	F5	
4	Context of the evaluation and choice of clinical data types. Outline the developmental context for the device. The information should include		
	Is the device based on a new technology, . The amount of inform differ according to the history of the technology. Where a completely new technology been developed, this section would need to give an overview of the development and the points in the development cycle at which clinical data have been generated. 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 equivalent device.		
	new clinical application of an existing technology		
	the result of incremental change of an existing technology		
	Identify the equivalent device(s) and provide a justification of the equivalency, cross-referenced to the relevant non-clinical documentation that support the claim.		
	State the Essential Requirements relevant to the device in question, in particular, 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.	C1;E4; E5; E9; E10; E11	
	Outline how these considerations were used to choose the types of clinical data use for the evaluation.	H4; H3	
	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.		
	Summary of the clinical data and appraisal		
5	Provide a tabulation of the clinical data used in the evaluation, categorised ace whether the data address the		

	performance or the safety of the device in question. (N individual data sets will address both safety and performance.) Within each category the data according to the importance of their contribution to establishing the s performance of the device and in relation to any specific claims about performance Additionally, provide a brief outline of the data appraisal methods used in the e including any weighting criteria, and a summary of the key results.		
	Include fill citations for literature-based data and the titles and investigation relevant) of any clinical investigation reports.		
	Cross-reference the entry for each piece of data to its location in the manufacturer's documentation.		
6	Data analysis		
6.1	Performance		
	Provide a description of the analysis used to assess performance. Identify the datasets that are considered to be the most important in contribution demonstration of the overall performance of the device and, where useful, performance characteristics. Outline why they are considered to be "pivotal" and demonstrate the performance of the device collectively (e.g. consistency of results, significance, clinically significance of effects).		
6.2	Safety;Describe the total experience with the device, including numbers and c patients exposed to the device; and duration of follow-up of device recipients. Provide a summary of device-related adverse events, paying particular attention adverse events.	Sales records	
	Provide specific comment on whether the safety characteristics and intended device requires training of the end-user.		
6.3	Product Literature and Instructions for Use	F2; F5	
	State whether the manufacturer's proposed product literature and Instructions for consistent with the clinical data and cover all the hazards and other clinically information that may impact on the use of the device.		
7	Conclusions		

	Outline clearly the conclusions reached about the safety and performance of the device from the evaluation, with respect to the intended use of the device. State whether the risks identified in the risk management documentation have been addressed by the clinical Data. For each proposed clinical indication state whether:		
	the clinical evidence demonstrates conformity with relevant Essential Requirements		
	the performance and safety of the device as claimed have been established		
	the risks associated with the use of the device are acceptable when weighed against the benefits to the patient		