Checklist for Clinical Evaluation Report Source Documents Requirement from Sponsor

No.	Particulars	
1	Device Name	Technical File Summary
2	Device Size (s)/Variant (s)	
3	Device Description & Features	
4	Classification of Device	
5	Performance Claims	
6	Material of Construction	
7	IFU	
8	Label	
9	Product Specification	Product Specification & Design
10	Certificate of Analysis	
11	Design History Data	
10	PMS Data	Data generated and held by the manufacturer
11	Sales Data (for 5 Years)	
12	Complaints (If Any)	
13	Product Recall (If Any)	
14	Adverse Reaction (If Any)	
15	Risk Management File	
16	Biocompatibility Test Result with followed standards or guidelines	
17	CE Status, NB	
18	Product Catalogue/Brochure	
19	Product Website link	
20	Company Logo (Use Authorization)	